

MESSAGE FROM PROFESSOR A BRECKENRIDGE, CHAIRMAN, COMMITTEE
ON SAFETY OF MEDICINES. 18 JULY 2002

Dear Health Professional

CSM ADVICE ON LIVER TOXICITY ASSOCIATED WITH KAVA-KAVA AND
PROPOSED REGULATORY ACTION BY THE GOVERNMENT

On the basis of the data available, the Committee on Safety of Medicines (CSM) has reached the provisional view that the possible therapeutic benefits of medicinal products containing the herbal ingredient Kava-kava (*piper methysticum*) can not be considered to outweigh the safety risks. Kava-kava is considered to have the potential to cause hepatotoxicity which may be serious. The level of risk is not known but is likely to be rare at normal doses. The mechanism of toxicity is not understood and there are no clear predictors of toxicity.

To date 68 cases of suspected hepatotoxicity associated with the use of medicinal products containing Kava-kava have been reported worldwide. These include cases of liver failure resulting in 6 liver transplants and 3 deaths. There have been 3 reports of liver toxicity in the UK suspected to be due to consumption of Kava-kava.

In light of the CSM's advice, the Medicines Control Agency (MCA) has decided to consult on a proposal to make an order under section 62 of the Medicines Act 1968 to prohibit the sale, supply and importation of unlicensed medicinal products containing the herbal ingredient Kava-kava. The consultation is to commence next week and will last for until 27 September 2002. MCA will use the information received during the consultation period when making their decision on whether to proceed with the order. In relation to a number of products which have marketing authorisations, the market authorisation holders have rights of appeal to the CSM.

Given the safety concerns surrounding the use of medicinal products containing the herbal ingredient Kava-kava, consumers are advised that, pending the outcome of the consultation process, it would be prudent that anyone taking such products should stop taking them. It is safe to stop taking the product(s) without visiting a doctor.

Healthcare professionals should ask about use of Kava-kava in all patients presenting with hepatotoxicity. Patients experiencing hepatotoxicity associated with Kava-kava have generally recovered on stopping.

Suspected cases of hepatotoxicity associated with Kava-kava use should be reported to the MCA/CSM through the Yellow Card Scheme. Yellow Cards are available in the back of the British National Formulary.

For further information, please call the MCA on 020 7273 0000.

Yours faithfully

Professor A Breckenridge
Chairman, Committee on Safety of Medicines