

MCA INVESTIGATION OF KAVA KAVA LEADS TO BAN FOLLOWING VOLUNTARY WITHDRAWAL

HERBAL MEDICINE BANNED FOLLOWING CASES OF LIVER TOXICITY

An Order prohibiting the supply of medicinal products containing Kava-kava will be laid before parliament on Monday, December 23 2002. The Order comes into force on January 13 2003.

This action follows concerns throughout Europe of liver toxicity, where all licensed Kava-kava products have been removed from the market. In the UK these concerns have been under investigation since December 2001, when a voluntary withdrawal of all stocks of Kava-kava containing products was undertaken by the herbal sector following advice from the Medicines Control Agency (MCA).

The Food Standards Agency has created parallel legislation to ensure that Kava-kava is no longer used in food products.

Following a public consultation, the Committee on Safety of Medicines (CSM) and the Medicines Commission have both concluded that there is clear evidence linking Kava-kava with rare cases of liver toxicity. The MCA is aware of 70 worldwide reports of adverse liver reactions. In four of these cases the patients died and in seven cases the patients required liver transplants. There have been four reports of liver toxicity in the UK thought to be due to consumption of Kava-kava.

Investigations have been unable to identify factors that would predict which individuals are at risk of adverse reactions to Kava-kava and the mechanism of liver toxicity related to Kava-kava remains unknown. The CSM and Medicines Commission were not reassured that the risk of liver toxicity could be reduced by measures such as label warnings.

In addition to Kava-kava, this situation has arisen before. There have been several cases where a conventional medicine or traditional medicine has been removed from the UK market over the last twenty years where evidence of rare but serious liver toxicity has emerged - for example, the anti-diabetic agent Troglitazone, withdrawn in 1997.

Professor Alasdair Breckenridge, Chairman of the CSM, said:

"Given the expert advice from the CSM and Medicines Commission following the recent public consultation it is clear that this ban is necessary.

"Kava-kava has been under investigation for 12 months as new evidence has gradually emerged and we are grateful to the herbal sector for its voluntary withdrawal of Kava-kava products back in December last year.

"The issues surrounding today's decision have been very carefully considered. A prohibition on safety grounds can be reviewed at any time if new evidence emerges and the MCA will be undertaking a specific review in two years time to assess whether this ban remains justified."

Dr Liz Williamson, herbals expert from the London School of Pharmacy, said:

"The liver toxicity associated with Kava-kava, although rare, is idiosyncratic. Because of the limited data available a risk to benefit assessment, which is routinely completed for all licensed medicines, is not possible. No specific risk factors have been identified and it is not possible to predict who is at risk before they use Kava-kava.

"In addition, no measures to reduce the risk, or the severity of liver reactions, are available. It is therefore in the best interests of patients that the herb be withdrawn at present.

"There are other useful herbal products which can be used for stress and related disorders."

Other countries have also taken action over Kava-kava products. In the EU all licensed Kava-kava products have been removed from the market while in Canada, investigations have concluded that there is insufficient evidence to support the products' safety and they have also been withdrawn from the market. In Australia products have been voluntarily removed from the market while an investigation is conducted and in the USA consumers have been warned of the risk of liver toxicity pending the outcome of an investigation by the FDA.

Notes for editors

The Medicines Control Agency (MCA) monitors the safety of all herbal medicines including unlicensed herbal remedies used in the UK using the same methods as used for conventional medicines. This includes the assessment of all reports of suspected adverse reactions received through the Yellow Card Scheme, which was extended to include unlicensed herbal remedies in October 1996.

The herbal ingredient Kava-kava is derived from the plant *Piper methysticum*, a member of the pepper family native to the South Pacific islands. It has been widely used in Europe for many years as a remedy for nervous states such as anxiety, tension and restlessness. In the UK there are a number of medicinal products consisting of, or containing, the herbal ingredient Kava-kava. The majority of these were supplied under the exemptions from licensing in respect of herbal remedies as set out in section 12 of the Medicines Act 1968.

The Order laid before parliament falls under Section 62 of the Medicines Act 1968 and will prohibit the sale, supply or importation of unlicensed medicinal products containing the herbal substance Kava-kava.

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