

# Kava fact sheet

April 2005

- Kava (also known as kava kava or *Piper methysticum*) is a member of the pepper family and has traditionally been cultivated by Pacific Islanders for use as a social and ceremonial drink - either ground or chewed up and mixed with water or coconut milk. Some Aboriginal communities are also known to use kava, however kava has not been a part of their traditional systems.
- Since 2001, the Therapeutic Goods Administration (TGA) has closely followed mounting international concerns over reports of hepatotoxicity and deaths from liver failure associated with taking some kava-containing medicines.
- Over this time the Complementary Medicines Evaluation Committee (CMEC) has recommended a cautionary approach as well as a series of appropriate practitioner and consumer alerts which the TGA has implemented.
- In July 2002, the TGA's Adverse Drug Reaction Unit (ADRU) received a report of a fatality in Australia, following acute liver failure, associated with a kava-containing medicine.
- A voluntary recall of kava-containing medicines regulated by the TGA was initiated in conjunction with the complementary medicine industry. This resulted in all kava-containing medicines being removed from the market place.
- Consumers were advised to discontinue use of kava-containing medicines, to return any unused medicines containing kava to the point of sale or take them to their local pharmacy for safe disposal.
- The forms of kava used traditionally by Pacific Islanders and by some aboriginal communities are NOT believed to be associated with the serious forms of liver damage.
- In January 2003, the TGA established an expert committee, named the Kava Evaluation Group (KEG), to review the safety of kava-containing medicines and to report to the CMEC as to whether it was appropriate to allow kava (*Piper methysticum*) to be used as an ingredient in 'Listed' (or low risk) medicines.
- The KEG brought together regulatory, kava and liver experts to comment on the safety of kava-containing medicines. The TGA, New Zealand Medsafe and both the Australian and New Zealand industry nominated experts for membership of the KEG. The process also included consideration of public submissions.
- The KEG considered a safety review of kava prepared by the TGA in early 2003, as well as other relevant information and made a number of recommendations to the CMEC regarding the regulation of kava-containing medicines. These recommendations addressed the different preparations and dosage forms of kava.
- At its meeting in August 2003, the CMEC considered the KEG report and recommended to the TGA that only certain forms of kava were suitable for use in Listed medicines. The TGA accepted the recommendations of the CMEC and the Therapeutic Goods Regulations pertaining to *Piper methysticum* were amended accordingly.
- The current restrictions for the therapeutic use of *Piper methysticum* are detailed in the [Therapeutic Goods Regulations 1990](http://www.comlaw.gov.au) <<http://www.comlaw.gov.au>>,

Schedule 4, Part 4, Division 2 (Plant material from which herbal substances may be derived for listable goods that are consistent with certain qualifications), Item 35.

- There is a limit on the maximum amount of Piper methysticum permitted per dosage form - for a tablet or a capsule, there is a limit of 125mg of kavalactones (a group of constituents found in Piper methysticum); and for a tea bag, there is a limit of 3g of dried rhizome (of Piper methysticum). In addition, all products containing Piper methysticum (any dosage form) must comply with a maximum daily dose of not more than 250mg of kavalactones.
- In addition, kava is classified as a prohibited import under the Customs (Prohibited Imports) Regulations. For more information on controls on the importation of kava, refer to: [Controls on kava: information sheet](http://www.tga.gov.au/import/kavainfo.htm)  
<<http://www.tga.gov.au/import/kavainfo.htm>>.