GOVERNMENT NOTICES
GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. 1223 **29 August 2003**

URGENT MEDICINE WITHDRAWAL

WARNING: SERIOUS HEALTH RISK – WITHDRAWAL OF ALL KAVA CONTAINING MEDICINES AND PREPARATIONS

The Medicines Control Council has decided that all medicines or dietary supplements and preparations that contain kava (*Piper methysticum*) are a serious health risk and should immediately be withdrawn from use.

The presence of kava in a medicine or supplement should be identified on the product label or box. The following are commonly used names for kava:

- ava
- ava pepper
- awa
- intoxicating pepper
- kava
- kava kava
- kava pepper
- kava root
- kava-kava
- kawa
- kawa kawa
- kawa-kawa
- kew
- *Piper methysticum*
- *Piper methysticum* Forst.f.
- *Piper methysticum* G. Forst.
- rauschpfeffer
- sakau
- tonga
- wurzelstock
- yangona

The Medicines Control Council (MCC) is advising consumers of the potential risk of severe liver injury associated with the use of kava-containing dietary supplements or medicines. Kava (*Piper methysticum*) is a plant indigenous to the islands in the South Pacific where it is commonly used to prepare a traditional beverage. Medicines or supplements containing the herbal

ingredient kava are promoted for relaxation (e.g., to relieve stress, anxiety, and tension), sleeplessness, menopausal symptoms and other uses.

Liver-related risks associated with the use of kava have prompted regulatory agencies in other countries, including those in Germany, Switzerland, France, Canada, United States of America and the United Kingdom, to take action ranging from warning consumers about the potential risks of kava use to removing kava-containing products from the marketplace. Although liver damage appears to be rare, the MCC believes consumers should be informed of this potential risk and that it is inadvisable to continue to use preparations containing kava.

Kava-containing products have been associated with liver-related injuries – including hepatitis, cirrhosis, and liver failure in reports of adverse events in other countries. Four patients required liver transplants. The Food and Drug Administration in the U.S. has received a report of a previously healthy young female who required liver transplantation, as well as several reports of liver-related injuries.

Given these reports, persons who have liver disease or liver problems, or persons who are taking medicines that can affect the liver, should immediately consult a medical practitioner or pharmacist to seek alternative therapy.

Consumers who are using a kava-containing medicine or dietary supplement and who experience signs of illness associated with liver disease should also consult their doctor or pharmacist for advice. Symptoms of serious liver disease include jaundice (yellowing of the skin or whites of the eyes) and brown urine. Non-specific symptoms of liver disease can include nausea, vomiting, light-coloured stools, unusual tiredness, weakness, stomach or abdominal pain, and loss of appetite.

The MCC urges consumers and their health care professionals to report any cases of liver and other injuries that may be related to the use of kava-containing medicines or dietary supplements. Adverse events associated with the use of medicines or dietary supplements should be reported as soon as possible to the National Adverse Drug Event Monitoring Centre at telephone number +27 21 447 1618 or Fax at +27 21 448 6181. Further details and the forms requiring completion are available in Regulation Gazette number 7659 published on 2 May 2003 (page 7) or can be downloaded from the MCC's website at http://www.mccza.com.

All persons who are in possession of kava containing preparations are instructed in terms of section 23 of the Medicines and Related Substances Act of 101 of 1965 (Medicines Act) to return these preparations to their point of purchase. Suppliers are instructed to return these products to the manufacturer or distributor.

The manufacturers or distributors are instructed to follow the recall procedures as detailed in the above-mentioned regulation and specifically section 9 thereof.

Any person not complying with the instructions issued in this notice is liable to prosecution.

No person shall sell any medicine or preparation containing kava that is the subject of this notice unless this decision has been set-aside on appeal (section 23(3) of the Medicines Act).

Any person not satisfied with the decision of the Medicines Control Council may appeal against this decision in terms of section 24 of the Medicines Act.

Yours faithfully

REGISTRAR OF MEDICINES

MEDICINES CONTROL COUNCIL