

Here follows an English translation of a statement released
by Commission E within Germany's BfArM that takes issue with
the recent action by BfArM related to kava

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American Herbal Products Association

The original German language statement from Commission E
can be found at <http://www.koop-phyto.org/>

Statement on Kava-kava by the members of the Commission E at the BfArM

July 2002

Statement

The undersigning experts in the field of phytopharmaceuticals, who are all members or representatives of the Commission E within the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM: Federal Institute for Drugs and Medical Products, Germany) comment on the withdrawal of the licence for medicinal products containing Kava-kava (rhizome of *Piper methysticum*) by the BfArM as follows:

The members of the Commission E express their astonishment at the action of the BfArM in the course of the drug safety procedure and the withdrawal of the licences for medical products containing Kava-kava. They consider that their scientific competence has been disregarded and that their function has been called into question.

In contrast to the BfArM, the members of the Commission E are convinced by the available scientific data on the efficacy of Kava-kava and assess the risk/benefit ratio and the therapeutic advantages for the patients as positive.

Unlike the BfArM, the members of the Commission E are of the opinion that there was no imminent danger which justified such a measure.

Furthermore, the members of the Commission E do not share the BfArM's opinion with regard to the risks when the product is taken in accordance with the instructions and consider the following recommendations to be necessary and adequate:

1. Medical prescription status for medical products containing Kava-kava.
2. Clear definition of indications: mild to moderate general anxiety. Depression is not an indication.
3. Maximal daily dose equivalent to 120 mg Kava pyrones.
4. Pack size with 120 mg Kava pyrones, max. 30 pce.

5. Normal duration of treatment 1 month, max. 2 months.
6. Measurement of liver values (GPT and gamma-GT) prior to the start of treatment and once per week thereafter.
7. Optional: Measurement of liver values at the end of treatment (important for any subsequent treatment).
8. Avoidance of concomitant medication with potentially hepatotoxic medication, particularly beta-blockers, antidepressants and migraine remedies. Caution needed with alcohol.

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