



The kava story continues. It has been over a year since the German BfArM (Federal Institute for Drugs and Medical Devices), followed by many other health authorities, banned one of most popular and best selling herbal drugs on the market: Kava (*Piper methysticum*). Since then, numerous papers providing information from "opponents" and "proponents" of this popular and effective herbal remedy have been pub-

(KEC), which will organize and coordinate all future actions.

Background

Kava has a long tradition of use in the South Pacific. For over 1000 years, a tranquilizing ritual beverage has been prepared from the rootstock of the plant. Based on its traditional use and sound scientific data documenting the safety and efficacy of kava preparations in numerous pharmacological studies and clinical trials, kava is definitely one of the best documented herbal drugs on the market—kava preparations were marketed as approved drugs in numerous countries. Drug monographs have been published by expert committees on herbal medicinal products, such as the German Commission E and the European Scientific Cooperative on Phytotherapy (ESCOP), confirming that kava is a safe and effective drug.

Kava was to be listed in the main section of a proposed German "positive list" alongside the most popular synthetic drugs. This list was created by an independent expert committee implemented by the German Health Ministry, meaning that only those drugs included had proven efficacy in the claimed indication and conform to the criteria of evidence-based medicine.

After the occurrence of a few cases of severe hepatotoxicity, claimed to be possibly be related to the intake of kava products, the German BfArM re-evaluated the benefit/risk ratio of kava and banned kava preparations up to a homoeopathic dilution of D4. Most other health authorities in Europe followed the decision of the BfArM, or asked producers to voluntarily recall their products. From one moment to the next, a traditional drink from the Pacific spontaneously mutated from a safe and effective drug into a dangerous substance.

A great number of specialists in the field of herbal medicine, pharmacology and toxicology, immediately reacted to this decision, claiming that case analysis by independent experts revealed that the vast majority of the

The Kava Executive Committee

An international committee has been formed in an effort to lift the ban on this popular herb.

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lished. Scientific experts in the field of pharmacology and toxicology, as well as pharmaceutical and herbal associations and practitioners, tried to persuade health authorities to rethink their decision and lift the ban, without any noticeable effect. Unfortunately, the regulatory situation remains unchanged.

Now it appears that a powerful international kava alliance will be formed, uniting the forces of stakeholders of various groups of interest, fighting for a re-evaluation of the herbal drug from the South Pacific. In late August, the first EU-ACP (European Union-African Caribbean Pacific states) Kava Stakeholder Meeting took place in Brussels, Belgium, bringing together key kava stakeholders from both the Pacific and the EU. The meeting was organized to serve as a discussion forum and to unite the different groups of interest to more efficiently strive to achieve a common goal. It resulted in the implementation of an international Kava Executive Committee

case reports could not definitely be related to the intake of kava and that the evaluation of the BfArM omitted many important facts, such as co-medication, alcohol and drug abuse or previous liver damage.

In March of this year, Phytopharm Consulting, Berlin, Germany, submitted an extensive report on the kava ban, raising further doubts about the reliability of the benefit/risk evaluation of the BfArM and other health authorities. The report was commissioned by the EU Center for Development of Enterprise (CDE) on behalf of some kava-producing countries in the South Pacific. The CDE critically evaluated whether the restrictions placed on kava by some European health authorities were justified. Among other things, it included an independent expert report on the pharmacological and clinical documentation of kava and a detailed case analysis of

the reported cases of hepatotoxic events.

The findings presented in the "In Depth Investigation on EU Member States Market Restrictions on Kava Products" clearly attested to the safety and efficacy of kava for the claimed indication and, in most aspects, confirmed the scientists regarding the kava ban as unjustified. Furthermore, the authors criticized the German health authority for having ignored and misinterpreted important scientific data in its evaluation and for giving kava an obviously distorted image.

Against the background of the findings presented in the Phytopharm report and the negative socio-economic impact in the developing kava producing countries of the South Pacific resulting from the kava ban, the CDE together with PRO€INVEST organized a working meeting that brought the affected stakeholders together. The

meeting served as an international forum, enabling the stakeholders to agree on a common strategy to get kava back on the agenda of European health authorities.

First EU-ACP Kava Stakeholder Meeting in Brussels

The EU-ACP Kava Stakeholder Meeting in Brussels represented the first attempt to form an international coalition requesting an independent re-evaluation of kava. It was sponsored by PRO€INVEST and the EU-ACP CDE. PRO€INVEST is a EU-ACP partnership program developed and undertaken by the European Commission on behalf of the ACP countries. PRO€INVEST is managed by the CDE under the supervision of the EuropeAid Co-operation Office of the European Commission. The CDE is a joint EU-ACP institution devoted to private

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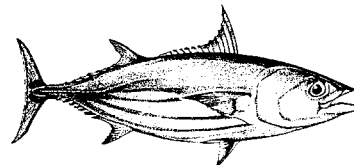
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sector enterprise development in Africa, the Caribbean and the Pacific under the Cotonou Agreement. The meeting brought together leading professional and scientific associations, herbal experts and representatives from the most prominent manufacturers of kava products in Europe, as well as leading exporters from the Pacific. It was also attended by representatives of international organizations such as the Pacific Islands Forum Secretariat (PIFS), World Health Organization (WHO), European Commission (EC), Technical Centre for Agricultural and Rural Cooperation ACP-EU (CTA), the Commonwealth Secretariat (COMSEC) and the embassies of Fiji, Samoa, Tonga and Vanuatu.

Major tasks of the Stakeholder Meeting

1. *Evaluation of scientific data on the safety and efficacy of kava.* One of the main goals of the stakeholder meeting was to discuss the actual state of scientific knowledge on kava research, as well as all other relevant information. Various renowned scientific experts contributing to this topic confirmed the findings presented in the Phytopharm Report, and agreed in that the benefit/risk evaluation carried out by BfArM was incomplete and misleading. Furthermore, the experts deeply regretted that the BfArM had not yet gained full access to the dossiers of the reported cases of hepatotoxic events. The contributions of independent experts clearly indicated that the bans, sales restrictions and market recalls by the regulators in respective EU countries, which were mainly based on the BfArM evaluation, be regarded as unjustified. Therefore, it was agreed upon to distribute the Phytopharm Report and request a re-evaluation of safety and efficacy of kava by an independent expert commission.

2. *Assessment of socio-economic impact of the kava ban.* The far-reaching consequences of the (possibly) unjustified ban of kava products seem to be largely underestimated. The meeting

revealed that the decision of European health authorities not only negatively affected the European producers of kava but also deprived patients suffering from anxiety and stress a safe and effective drug. The restrictions on kava

“...(The KEC) signifies for the first time that health authorities are facing a united kava front.”

have also led to economic disaster in the kava-producing South Pacific Island states of Fiji, Samoa, Tonga and Vanuatu, which was not widely known to the public in the northern hemisphere. Due to the discontinuation of the European markets caused by the ban, a developing industry for these lesser developed states was destroyed literally overnight. According to the officials of these states, since 2001 the loss of local export earnings in the South Pacific has amounted to more than \$200 million. Furthermore, most farmers dependent upon the cultivation of kava have now lost their only source of income, so that the livelihood of many rural communities is now being seriously threatened.

3. *Development of a detailed action plan.* Against the backdrop of the scientific data presented and the contributions regarding the negative socio-economic impact of the kava ban, stakeholders together with official observers discussed the strategic options available to revoke the ban. The participants finally agreed on a strategy proposed by Phytopharm Consulting and the Pacific Islands Forum Secretariat.

Implementation of the Kava Executive Committee (KEC)

As a first step toward better coordination of all further actions taken by the

affected stakeholders, the participants agreed on the implementation of the Kava Executive Committee (KEC). The KEC will consist of elected stakeholders from both the Pacific and the EU. It will be comprised of delegates from national and international associations, as well as representatives of the kava industry, producers and traders. The KEC will be responsible for the realization of the detailed action plan, which was created jointly at the meeting in Brussels, within a proposed time frame, and will be responsible for all immediate and future issues related to the management of kava. Furthermore, the committee will inform stakeholders of

its progress and will operate as an advisory board for all kava stakeholders. The organizers of the Brussels meeting will also organize the initial meeting of the KEC. In the starting phase the KEC will be sponsored by PRO€INVEST and the CDE, which will also provide technical assistance and lobbying support. This will enable the committee members to perform the first steps as quickly as possible. The first meeting of the KEC is planned before the end of this year. One of the primary tasks of the KEC will be the development of a powerful lobbying strategy to increase the pressure on the responsible authorities to re-evaluate the “kava case.”

Summary

The Brussels Kava Stakeholder Meeting leading to an international “kava alliance” and the implementation of the KEC represents an important step forward in the endeavors of stakeholders to revoke the unjustified ban on kava. It also signifies for the first time that health authorities are facing a united kava front. The committee’s progress, however, will depend on the effort that individual stakeholders are willing to invest in the issue. Taking into consideration what has been achieved in Brussels and how stakeholders are working on the first KEC Meeting, one can risk an optimistic view into the future of kava. ■