

When the representatives of the International Kava Executive Council (IKEC) left the German Health Ministry in Berlin, Germany, in April this year, a major breakthrough was achieved with regard to the ban of kava products. The discussions with the German Deputy Health Minister resulted in the first commonly agreed approach to determine an appropriate design for the generation of new data. The results obtained from these data may finally

representatives of national pharmaceutical and herbal associations, scientific experts, kava growers and kava producers, and is comprised of delegates from both the Pacific and the EU.

Since its inception, IKEC has significantly improved the organization, cooperation and the flow of information between kava stakeholders. In addition, some of the goals proposed at the stakeholder meeting have already been achieved (see Eurotrends column in January 2004 issue). This includes the World Health Organization (WHO) decision, in November last year, to re-evaluate all the available data on kava due to the unclear scientific situation and the data presented in the Phytopharm report. Although the WHO can only recommend, the results of this evaluation may increase the pressure on health authorities to re-evaluate their decisions. Pressure also intensified at the political level for the governments of the affected South Pacific states. These states put the kava issue on the political agenda of the Commonwealth and the ACP (African Caribbean Pacific) group of states. In February 2004, the ACP group of states enforced a resolution at the ACP-EU Joint Parliamentary Assembly meeting in Addis Ababa, Ethiopia. This resolution called on the concerned EU Member States to urgently review, on the basis of scientific evidence, the ban and restriction on, and market recalls of, kava and kava-based products in the EU member states.

Breakthrough In Kava Debate

Significant gains have been made in the kava discussions with health authorities in Europe.

By Joerg Gruenwald & Juergen Skrabal

put the issue of the safety of kava to rest. This "Berlin approach" represents great success, which could have a major influence on the decisions of health authorities around the world, quite possibly leading to a re-evaluation of kava.

In their discussions with the German and British health authorities, the IKEC representatives were supported by the Fijian and Samoan High Commissioners to the U.K. and Ambassadors to Germany, as well as renowned scientific experts in the field of pharmacology and toxicology and healthcare practitioners.

The IKEC

Against a background of doubtful scientific justification for the ban and its severe impact on the economy of the South Pacific Islands states, the scientists and stakeholders, who met at the International Kava Stakeholder Meeting in Brussels, in August 2003, proposed to join forces in an international organization (see Eurotrends column in November 2003 issue). Three months later, the International Kava Executive Council (IKEC) was officially established. The IKEC (www.ikec.org) is an international non-profit organization focusing on re-establishing the kava trade between the kava-producing South Pacific Island states and Europe. It consists of repre-

IKEC's Most Recent Progress

The Berlin meeting of the IKEC was initiated to inform all parties involved of the progress that has been made. Furthermore, the meeting updated all parties involved on what had been achieved thus far. Lastly, it evaluated the current strategy and discussed further immediate and future strategy.

Among the main topics discussed were the safety of kava and the establishment of an improved quality control system. In this context, all delegates declared their willingness to secure the quality and safety of kava, and agreed to:

- Define acceptable parameters for industry standards concerning kava

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quality, as a basis for future legislation, in cooperation with the European delegates and representatives of the South Pacific.

- Support scientists from Europe and the South Pacific to identify the best and safest kava varieties, which will conform to the stipulated standards.
- Establish an exemplary quality control system, with defined standard operating procedures (SOPs), which will be highly efficient and a great improvement over the present system. This will guarantee that only the best kava varieties are used. This high quality kava shall then be marked with a controlled South Pacific Kava Quality Seal.
- Identify and investigate hypotheses explaining possible mechanisms that could possibly have led to the few potentially toxicological effects of kava preparations. (However, all members, again, pointed out that kava itself is safe and that currently the theory of toxicological potential, claimed by health authorities, has not been proven and relies solely on a doubtful evaluation, based on insufficient data presented in mainly incomprehensive case reports.)

Quality and safety will also be one of the main topics of the "International Kava Conference", which is currently scheduled for November 24-26 this year in Suva, Fiji. The conference will be coordinated and organized by IKEC, in close cooperation with the Fiji government, the Fiji School of Medicine and the Pacific Islands Forum Secretariat (PIFS). The proposed sessions will deal with new investigations on the safety and efficacy of kava, the regulatory situation, as well as economic issues and future perspectives. Details of the International Kava Conference and a detailed programme will be determined in the close future and announced by the IKEC.

Successful Meetings with German and British Health Authorities

The first talks, which took place at the German Health Ministry, at the request of the IKEC, were a great success. For the meetings, the German Deputy Health Minister, Dr. Klaus Theo Schroeder, had invited renowned scientific experts, practitioners and representatives of IKEC, as well as H. E. Eritai Boladuadua and H.E.

Tau'ili'ili Uili Meredith, the Fijian and Samoan High Commissioners to the U.K. and Ambassadors to Germany. A representative of the British Embassy also attended the meeting. In the discussions, Deputy Health Minister Dr. Schroeder fully acknowledged the significance of kava for the Pacific region and declared the evaluation of safety and efficacy of kava as an "issue of highest importance and priority".

The participants also discussed the requirements, which must be met in order for kava to again be made available for patients suffering from stress, restlessness and mild degrees of anxiety. During the constructive discussions, it was agreed that further research activities will focus on the safety of kava first, before discussing its efficacy.

All participants expressed their commitment to re-evaluating the safety of kava within the next six months. Deputy Health Minister Dr. Schroeder, therefore, called on representatives of the German Health Ministry, the IKEC and independent experts in the field of pharmacology and toxicology to join together to determine an appropriate design for the generation of new data. Representatives of the IKEC are confident that this data will confirm the results of other studies and show that kava is a safe herbal.

The results of the toxicological research being proposed may also contribute to the kava safety evaluations in other countries, where kava is currently prohibited or under debate. During a meeting of the delegation with the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), which took place on April 2nd, in London, the MHRA expressed considerable interest in the German approach to creating new data. It stated that the agency welcomes a dialogue on this issue and will consider the results of all new research.

Due to the positive conversations that have taken place with the German and British health authorities, kava producers have also expressed their interest in creating a harmonized approach to re-evaluating the safety and efficacy of kava. In a recent meeting with the IKEC, 10 German producers of kava products confirmed their contribution to the new study. Stay tuned... NW

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