

KAVA REPORT 2003

IN-DEPTH INVESTIGATION INTO EU MEMBER STATES MARKET RESTRICTIONS ON KAVA PRODUCTS

EXECUTIVE SUMMARY

Prepared for

CDE

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1. Introduction

On behalf of the negatively affected South Pacific member states, the Pacific Islands Forum Secretariat (Suva, Fiji) requested to the Centre for Development of Enterprise (CDE, Brussels, Belgium) for assistance, resulting in the engagement of Phytopharm Consulting (Berlin, Germany) by CDE to perform the present “In-depth Investigation into EU Member States Market Restrictions on Kava Products”. The objective of this project is to provide sound scientific background information to evaluate if the kava restrictions are justified. Phytopharm Consulting has reviewed and evaluated all available cases and scientific information on kava, the restrictive measures taken against kava by health authorities, and the resulting economic consequences for the negatively affected South Pacific islands. Based on this extensive analysis a possible future strategy to restore kava’s reputation as safe and effective prescription drug was developed.

2. Summary of Results

2.1. Scientific Evaluations

The efficacy and safety of kava in the treatment of conditions of nervous anxiety, stress, and restlessness has over two thousand years of traditional use and is proved by 20 clinical trials including more than 10,000 patients and supported by post marketing experience in Europe, the USA and other countries and by several expert commissions implemented by the German Health Ministry. The severe hepatotoxic effects of kava, claimed by drug regulation authorities, cannot be regarded as proven. From the 76 reported cases we have examined and evaluated, only 4 of them may possibly be related to the intake of kava. All experts criticized the conclusions having been made by regulation authorities as the German BfArM on the basis of insufficient data provided by the relevant case reports. Numerous experts and even health authorities as the American Food and Drug Administration (FDA) agree with our analysis and confirm kava as being an effective and safe herbal remedy without the potential of severe hepatotoxic side effects, if used properly according to the medical instruction. The benefit-risk-ratio for kava evidently has to be regarded as positive and the withdrawal of market authorization of kava preparations as unjustified.

2.2. Economic impact

The current kava restrictions are an economic disaster for the producers and traders in the South Pacific Islands, particularly those situated in Fiji, Hawaii, Samoa, Tonga and Vanuatu.

In recent years, there has been developed a promising market for kava because of the increased worldwide demand for kava. In 1998, when the export figures from South Pacific islands reached its peak level it was among the top-selling herbs in the U.S. and among the fastest-growing herbs with a growth rate of 473% from 1997 to 1998. In the South Pacific region the annual production of kava was estimated of about US \$200 million. In the U.S., kava was wide spread in the nutraceutical and food supplement market. The pharmaceutical market was centered in Germany with an estimated 1.3 million users.

Consequently, the area of land planted with kava in the South Pacific has augmented to around 10,000 ha. to fulfill the increased worldwide demand. Therefore, the livelihood of many South Pacific people was/is heavily dependent on a productive kava business.

But the negative publicity from the kava bans and market recalls has greatly disadvantaged the growing kava industry, and exports from the South Pacific to the European and U.S. markets came to a halt in late 2001. In consequence, the domestic price of kava has severely declined and important export earnings for the South Pacific islands have been lost. The Pacific Islands Forum Secretariat has been actively supporting its affected member states since the end of 2001 in order to find solutions to the economic kava crisis.

Also many pharmaceutical companies using kava were confronted with severe profit setbacks. The negative economic consequences are also clearly documented by our communication with South Pacific kava producers and traders as well as kava-using pharmaceutical companies.

3. Future Strategy

Based on our detailed scientific analysis we developed an argumentation chain and strategic action plan to rebut the ban on kava in most European states.

First we suggest focusing primarily on the most realistic goal: to regain the market authorization for kava products as prescription drug with the respective labels providing its safe and controlled use. This long-term objective needs several strategic steps to be realized. In the first place we recommend claiming for the official opening of the evaluation of the kava case reports carried out by BfArM and used by the health authority to justify the withdrawal of marketing authorization of all kava-containing food and medicinal products with immediate execution. The documents then should be re-evaluated by an independent and officially acknowledged scientific expert committee. This counter report, if coming to opposite conclusions, would be of highest priority to achieve a legally accepted positive re-assessment of kava as safe and effective remedy.

Since it was univocally criticized by numerous renowned scientists and experts that the BfArM report is bearing fundamental shortcomings and inconsistencies, which must not have been used as lawful argumentation basis to ban kava.

This claim for the opening of the documents against the health authorities should be initiated and coordinated by a yet to be implemented “Kava Executive Committee” consisting of delegates from relevant organizations and associations, the Pacific Islands Forum Secretariat, the CDE, kava-exporting FICs (Forum Island Countries), respectively Pacific ACP member states, scientific experts, the phytopharmaceutical and herbal products industry, and ourselves (Phytopharm Consulting).

This international committee should organize and coordinate all further actions. One crucial issue represents the initiation of additional research corroborating the safety and efficacy of kava. The committee should initiate and coordinate new research to further document that kava is a safe and effective medicinal plant. All positive sources should be approached and a co-operative research program should be started as soon as possible.

As additional step of high priority, the committee should submit a dossier including the present expert report of Dr. Gruenwald including his “Comments on the BfArM Decision” to the World Health Organization (WHO) requesting a positive scientific evaluation of kava by an independent expert commission.

Based on this positive evaluation of the WHO together with our evaluation, one of the affected Pacific ACP member states should turn to the Advisory Centre of the WTO Law (ACWL) and ask for legal advice and support in WTO dispute settlement proceedings. Simultaneously, a strong, internationally coordinated, PR campaign should be initiated to draw public attention on the Kava “tragedy”.

All these actions by CDE, the Pacific Islands Forum Secretariat, WHO, WTO, the Pacific ACP member states (respectively FICs), Phytopharm Consulting, the phytopharmaceutical and herbal products industry as well as the public should finally result in the positive re-evaluation of kava by European Health authorities leading to the rebuttal of the worldwide kava bans and the restoring of the financially stricken kava producers and traders in the South Pacific islands.