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Resolutions of IKC 2004

The International Kava Conference (IKC) was organized by the International Kava Executive Council (IKEC) in Suva, Fiji on 30 November – 2 December 2004. The Conference was sponsored by Centre for the Development of Enterprise (CDE), ProInvest, Pacific Islands Forum Secretariat (PIFS), Fiji School of Medicine, University of the South Pacific, Secretariat of the Pacific Community and the Government of Fiji. The main objective of the Conference was to discuss new scientific data on safety and efficacy of kava in order to remove the current bans and restrictions on kava and its derivatives in key export markets. Participants included kava stakeholder representatives, scientists, health authorities and academics from 16 countries including the Pacific African Caribbean Pacific (ACP) and European Union (EU) States.

The Conference was officially opened by the Prime Minister of Fiji, Hon. Laisenia Qarase, with introductory remarks also delivered by the PIFS Secretary General, Mr Greg Urwin. They both acknowledged the contributions of IKEC as well as all sponsoring institutions and sought the continued support of donors towards addressing the kava cause. The Prime Minister urged all concerned to strive towards the removal of the bans and restrictions as this would help restore much needed income for rural households in particular. Amongst the measures he suggested to effect this, was the harmonisation of kava legislation in the region to ensure that export market requirements are fulfilled by producers and exporters in the Pacific. The Secretary General highlighted that the kava industry is an important element of regional economic development and will thus play a key role in supporting the goals of the Pacific Plan.

As a matter of priority, we the IKC participants noted:

- a) **That after the deliberations and presentation of new scientific evidence during the Conference, we see no grounds for the continuing bans and restrictions. We therefore call for their immediate removal by all the relevant regulatory authorities including those in the EU.**
- b) **The Pacific Island kava-producing countries need to be urgently supported in their efforts to strengthen the kava industry and re-establish its export markets.**
- c) **The Pacific Island Countries are committed to producing quality products by establishing and maintaining internationally recognised standards and specifications.**

To achieve the above, the IKC participants endorsed the following evidences as submitted by scientists to the Conference:

Scientific Resolutions

1. With kava extracts produced in Europe, a number of case reports of liver toxicity were filed to the health authorities. A total of 4 cases were identified as being probably related to kava extract intake. Even accepting that all 82 reported cases are causally related, the incidence rate is one case in 50 million kava extract users. It was considered therefore that the reaction from the regulatory authorities in the EU member states appears to be disproportionate to the alleged problem.
2. It is recognized that the federal authorities of the United States of America informed consumers about potential problems and advised the industry to institute cautionary labelling as an alternative to banning kava. The IKC participants resolved that other countries should consider this option.
3. The World Health Organisation (WHO) was requested to work on kava safety evaluations as soon as possible. WHO is asked to collect detailed information from all available sources on case reports and specifications of products used in the corresponding ADR cases. The WHO was further requested to review any other information relating to kava safety/toxicity and, to communicate the review findings to its member countries. The Governments of the Pacific region were encouraged to support the WHO in this regard.
4. Sufficient evidence in well-controlled clinical trials is available for kava extracts in the treatment of anxiety. However, in order to lift the kava ban, the German health authorities have requested additional clinical data which may require substantial financial resources. Furthermore, authorities including WHO and MHRA shall be asked to consider the outcomes of the two scientific reviews (meta-analyses) done by independent authors.
5. To date, investigations suggest a hypothesis that the causal factors to the case reports may be related to the variety of kava utilized, and possibly the extraction method. This hypothesis needs to be tested. However, new toxicity tests using liver cells and whole animals showed no toxicity at relevant doses.
6. IKC called for the support from Post Forum dialogue partners including the French government to re-establish the important research work of the CIRAD in the Pacific on the cultivation and processing of kava.
7. IKC called on the European Pharmacopoeia to restart the preparation of a monograph on *Piper methysticum*.
8. It is recommended that precise technical specifications are developed and implemented as a "gold standard" for kava raw material with stringent quality control measures in the

Pacific to ensure that only suitable kava varieties are grown and marketed. The gold standard should include a state-of-the-art chemical fingerprint to represent the spectrum of ingredients. Full traceability and compliance to GACP and GMP should be documented with each shipment. These measures need to be audited through an accredited organisation. IKEC is asked to establish the necessary framework.

The IKC participants also noted and agreed to support the following:

IKEC Activities

1. That IKEC continues implementing the Kava Strategy as agreed to at the Brussels Stakeholders Meeting in August 2003 continues. The present research and public relations campaign to mitigate the negative publicity on kava are to be intensified. IKEC should also generate new data to facilitate the lifting of the bans/restrictions and source the necessary funding support to pursue its activities.
2. It was agreed that IKEC be formally incorporated as a representative organization of kava producer associations, exporters and importers and other players, representing all stakeholders in the kava industry.
3. The scientific community acknowledged and respected the different forms of kava preparations (kava powder and water-based beverages) that have been in use for centuries. The scientists further agreed that these modes of preparations could be safe as long as traditional methods of choosing kava cultivars and plant parts are followed. Specifically, only certain varieties have been found to be suitable for daily use hence, it was agreed to promote the efficacy and safety of the traditional product for use by international consumers.
4. IKEC is to evaluate and plan for the registration of a selected kava product under the EU Traditional Herbal Medicinal Products Directive (THMPD EC 2004/24).

The IKC participants further sought support in the following areas:

Capacity Building and Networking

1. Training programmes are to be developed to enhance quality and capacities at all levels of the kava production and value-adding chain. This should include farmers, processors and exporters. The exchange of information and sharing of experiences amongst stakeholders and key institutions are to be encouraged and supported as this would also facilitate regional quality and capacity building. Technical assistance and training and the establishment of appropriate quality control management systems at the production and processing level (GACP, GMP) have to be established.

2. Stakeholders while taking advantage of impending global opportunities for kava and its related value-added products should also take the necessary steps of patenting, branding of Pacific Kava, including intellectual property rights.

Funding and Partnerships

1. IKC appreciated the strong support of CDE and PROINVEST in financially backing the kava reinstatement project. IKEC is directed to work with CDE, PROINVEST, the ACP secretariat and CTA to establish a work plan for the future work and the funding thereof.
2. Public-Private Sector Partnerships between kava stakeholders within the Pacific and in Europe as well as with the international donor community should be strengthened to effectively address present concerns on the bans/restrictions and also tap the future global market potential for kava and its products.

In closing, the Executive Director of IKEC thanked the participants, including the speakers and all of the supporting institutions for their contributions and urged their continued assistance and cooperation towards the successful implementation of the outcomes to which they had agreed.

IKEC

Suva, Fiji

3 December 2004