



In June 2002, the German BfArM (Bundesamt für Arzneimittel und Medizinprodukte/Federal Institute for Drugs and Medical Devices) was the first health authority to ban all kava-containing preparations on the basis of a revised benefit/risk ratio, after the occurrence of a few severe adverse events supposedly related to kava intake. Immediately following this, bans, restrictions and market recalls took place in numerous other Euro-

measures taken by the German BfArM were inappropriate and unjustified.

Due to these findings and on behalf of the Pacific Islands Forum Secretariat (PIFS), the EU Center for Development of Enterprise, together with PRO€INVEST, organized the first EU-ACP (European Union – African Caribbean Pacific Group) Kava Stakeholder Meeting, which took place in Brussels, Belgium, in late August last year. The meeting was the first attempt to form an international coalition to search for ways to re-introduce kava to the market. In attendance were representatives from international organizations such as the PIFS, World Health Organization (WHO), European Commission (EC), Technical Centre for Agricultural and Rural Cooperation ACP-EU (CTA), the Commonwealth Secretariat (COM-SEC) and the ambassadors of Fiji, Samoa, Tonga and Vanuatu.

It has been three months since the first EU-ACP (European Union-African Caribbean Pacific Group of states) Kava Stakeholder Meeting took place, bringing together key kava stakeholders from both the Pacific and the EU. Among several developments, the meeting established the International Kava Executive Committee (KEC). This committee includes delegates from both the Pacific and the EU and will co-ordinate the future actions to re-establish the kava trade between the EU member states and the South Pacific kava producing countries. It appears that this powerful international kava alliance, which unites stakeholders from various interest groups, has now achieved its first major goals.

WHO to Re-Evaluate kava

One of the first tasks of the KEC was to request re-evaluation of all the available scientific data concerning the safety and efficacy of kava by an independent organization, such as the World Health Organization (WHO). Therefore, the KEC submitted a copy of the Phytopharm report to the WHO with a request that it be forwarded to the

WHO To Re-Evaluate Kava

An international kava alliance formed several months ago has achieved its first major goals.

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pean and non-European countries. Most of these decisions were based on the BfArM's revised evaluation on the safety and efficacy of kava. Due to the negative publicity resulting from the actions of several health authorities, kava disappeared from the shelves of pharmacies and drug stores across Europe. As a consequence, the kava trade between European member states and the kava producing South Pacific Island states ground to a halt, leading to socioeconomic disaster in Fiji, Samoa, Tonga and Vanuatu. Against this background, the EU Center for Development of Enterprise commissioned Phytopharm Consulting, Berlin, Germany, to investigate whether or not the restriction on kava products were justified. The results of the Phytopharm report, "In Depth Investigations on EU Member States Market Restrictions on Kava Products," revealed that kava be regarded as a safe and effective medicine, and criticized the health authorities for having omitted important details in their evaluation and creating a distorted and misleading image of kava. Furthermore, the authors noted that the

responsible division, and that a re-evaluation of kava be initiated. It now looks as if the findings of the Phytopharm Report and the follow-up activities of the KEC are beginning to show results.

In its November 29th, 2003 press release, the WHO confirmed that it had decided to re-evaluate kava and that the ACP Council of Ministers had drafted a kava resolution, which made kava a political issue.

In the first meeting of the Advisory Committee on Safety of Medicinal Products (October 20-22, 2003, WHO, Geneva), the committee endorsed the recommendation to obtain data/assessments from countries where kava use was associated with available adverse reaction reports, including comprehensive literature reviews. According to expert sources, the WHO has involved two of its Pharmacovigilance Centers in the evaluation process, one in Europe and one in the Pacific.

This represents an opportunity to obtain a comprehensive, accurate evaluation of kava, which should include all the data and publications that were published before and after kava was banned in several countries. To support the work of the two pharmacovigilance centers involved in the re-evaluation of kava, the KEC will provide the responsible investigators with the Phytopharm report and all other helpful information on the safety of kava.

Kava Resolution of the ACP Council of Ministers

As mentioned previously, the stakeholder meeting was also attended by the Ambassadors of the kava producing South Pacific Islands states of Fiji, Samoa, Tonga and Vanuatu. The

Ambassadors endorsed the organization of the kava stakeholder meeting and the establishment of the KEC. They also said that they would discuss the kava issue with the responsible politicians in their countries, as well as put it on the agenda of the ACP Council of Ministers. The ACP group is an inter-governmental organization that was established by the Georgetown Agreement, initially signed on June 6, 1975. The group comprises 78 states in Africa, the Caribbean and Pacific, including a majority of the Least Developed Countries (LDCs) in the world.

In a special session of the ACP Council of Ministers held on October 1, 2003, in Brussels, the Council drafted a resolution on kava. In its resolution the Council of Ministers indicated that they deeply regretted that the German BfArM and many other health authorities of EU member states had banned or restricted the sale of kava-containing products on the basis of a very questionable evaluation of scientific data, against the recommendation of many scientific experts. In its statement, the Council referred to the conclusions presented in the Phytopharm report and explicitly endorsed the findings presented there.

In their resolution, the Council of Ministers calls on the EU to:

- Recognize that the unjustified and inappropriate measures taken by some EU member states' health authorities are affecting the least developed or developing island states with specific economic and social difficulties. These countries need the kava export earnings for their sustainable socio economic development.
- Recognize the significant and vital

contributions the kava export earnings have made to sustainable economic development, poverty alleviation and the fight against social exclusion resulting from globalization in ACP states.

- Recognize that the numerous bans, restrictions and market recalls of kava products has resulted in an economic disaster for the kava producing ACP states, a destroyed export market, which in turn lead to bankruptcies, and is threatening the livelihood of thousands of people in these underdeveloped rural communities.
- Acknowledge the multifunctional nature of the kava sector, particularly its role in environmental protection and rural development in kava producing ACP states.
- Support the efforts and initiatives of the kava producing ACP states at the World Trade Organization (WTO) to amicably resolve the matter in the interest of all concerned parties.

The Council of Ministers requested further that the President of Council forward this Resolution to the Council of the EU, EU member states, ACP-EU Joint Parliamentary Assembly (JPA), European Parliament and the European Commission.

This resolution represents a major step forward in emphasizing the far-reaching consequences, which resulted from a ban that must at least be regarded as highly questionable. It is hoped that the responsible politicians in Germany and the other European countries will now recognize the vital importance of kava for the socio economic development of some of the least developed countries and rethink the actions taken by their health authorities.

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