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EDITORIAL

Time for a reassessment of the use of Kava in anxiety?

Seven years after the ongoing ban of *Piper methysticum* (Kava) by the EU, UK and Canada: Where are we at? In December 2008, articles by the *Fiji Times* reported that the Kava ban was over-turned. This statement was subsequently revealed to be erroneous and is indicative of the controversy and confusion sometimes surrounding regulatory, safety and efficacy issues associated with Kava.

Cases of hepatotoxicity purportedly caused by European Kava products may have been due to a commercial cost-motivated preference for injudicious Kava cultivars or plant parts, and the use of non-traditional solvents (ethanol and acetone).[1] Conversely, traditional use of Kava (<100 g per week) is associated with remarkably few adverse effects in Pacific Island communities,[2] and public health concerns instead centre on issues of abuse by heavy users.[2—5]

A puzzling and often overlooked motivation for the initial Kava withdrawal by BfArM (German drug regulatory body) was due to a purported lack of efficacy. This position belies the current evidence with meta-analyses demonstrating statistically significant efficacy in treating anxiety.[6] As such, the twin challenges of safety and efficacy need to be addressed in order to re-establish Kava in the global market.

The outcome of a meeting in October 2008 involving the International Kava Executive Council (IKEC), the German regulatory authorities and the EU commission was to develop a road map of legal, scientific, regulatory and manufacturing requirements necessary for the re-introduction of Kava. IKEC is currently exploring novel ways in which it may be possible to re-introduce Kava to restricted markets, including re-classifying Kava as a traditional medicine. The way forward will require the creation of a Pacific quality control system principally involving Vanuatu, Fiji, Tonga and Samoa. Kava products should ideally only be manufactured from aqueous extracts from peeled rootstock of 'noble' Kava cultivars (as other cultivars (e.g. tudei and wichmanni) are much higher in kavalactones such as dihydromethysticin, and may cause unwanted adverse effects).[1]

As both Lebot and Schmidt have previously outlined, the adoption of a geographical 'origin of protection' system (whereby products are strictly classified and titled based upon place of cultivation) may not only promote a confidence in efficacy and safety, but may also provide sufficient protection of intellectual property for those traditional communities involved.[7,8] Most of the health concerns associated with Kava have occurred from non-traditional formulations, and as such it seems unreasonable and unjust that developing Pacific economies are currently penalised in terms of not having sufficient protection of their traditional commodity and the right to export it globally. For this to be a viable commercial reality, protection of the formulation of any newly developed Kava products may be required. One possible means of achieving this may be by standardising via specific chemotypes using the Lebot system, which involves the six major kavalactones (numbers 1—6).[8]

The restriction of Kava's importation has not only resulted in the removal of an effective anxiolytic but has also detrimentally affected Pacific Island economies. Prior to the ban, annual production of Kava by Pacific Island communities was approximately $200 million per annum.[9] After the ban in 2002, farm revenues from the sale of Kava in Fiji, Vanuatu, Tonga and Samoa decreased between 75 and 98%.[9] This has particularly affected historically disadvantaged native and rural populations in these countries. For example, in Fiji the disadvantaged native population constitute approximately 98% of all Kava farmers, [5] and Kava production was one of the few profitable industries run by this population.

While the way forward for Kava will no doubt be challenging, progress is nonetheless occurring, and with the support of governments and industry and the practice of rigorous science, the future of the medicinal plant and the Pacific Island communities it supports remains optimistic. With the development of definitive guidelines regarding the necessary clinical and toxicological evidence and the introduction of a strict Pan-Pacific quality control system, re-introduction of this effective and safe anxiolytic agent may be achievable in the near future.

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Conflict of interest

None.

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