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German Court Reverses Ban of Kava Products

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Key Points at a Glance

Timeline: Restriction of Kava Products

November 2001	German Health Authority (BfArM) announced its intention to ban use of kava on the basis of a few suspected cases of a rare hepatotoxic reaction.
2002	Kava products banned in Germany.
2002-2003	Other countries including Japan, France, Canada, United Kingdom and Switzerland banned kava products.
July 2002	Therapeutic Goods Administration (TGA) initiated a voluntary withdrawal of kava products.
January 2003	TGA established an expert committee, named the Kava Evaluation Group, to review the safety of Kava-containing medicines. – Kerry Bone participated as an industry expert. – Public submissions were allowed: MediHerb prepared a 119-page submission that included critical review of the case reports and testimonials from patients who benefited from the use of kava.
August 2003	TGA decided only certain forms of kava (those made from water extract/dispersion or whole rhizome) could be used in listed medicines. The maximum daily dose of kava lactones could not exceed 250 mg. (Although, under state law, kava cannot be sold to practitioners or the general public in Western Australia.)

On 11th June 2014 a German administrative court ruled that there was no justification for the German government's ban on kava products, which had occurred in 2002. It was noted in the judgement that the benefit-risk ratio for kava-containing medicines was confirmed as positive. As a consequence, the marketing authorisations for kava products in Germany have been formally restored – these kava products can be sold. BfArM, the government department responsible for the original ban, lodged an appeal against the court's ruling on 30th June 2014, so it may not be over yet.

At the time it was hard to understand why the action was taken against kava. The "ban" of kava frequently was misunderstood as a safety measure to protect the population from kava. In reality, the ban (technically a removal of marketing authorisation to sell kava products) was the result of a complex regulatory issue. Dr Mathias Schmidt, a scientist who has been working in the area of herbal quality and safety, especially that of kava, since 2000 has carefully explained this complex topic for English readers in the American Botanical Council's HerbalEGram and *HerbalGram*.

In brief, the regulatory procedure used to assess the benefit-risk ratio when the small number of case reports of potential liver toxicity came to light in 2001, was problematic.

- BfArM did not look at the use of the kava plant, but narrowed their focus to the specific extracts on the German market.
- They created new rules that discarded all clinical studies prior to 2001, leading them to the conclusion that there was no proven efficacy for the kava products, which consequently produced a negative benefit-risk ratio.
- There was no causality assessment conducted on the case reports at the time. (Assessments by experts conducted in 2009 and 2010 on this data found low risk i.e. a positive benefit-risk ratio.)
- Around the time of the BfArM benefit-risk assessment, they declared kava to be a 'new and unknown drug entity'. This change caused confusion as to the type and amount of data that manufacturers needed to present to receive market authorisation for kava products. The supporting evidence would also have to be delivered as Good Laboratory Practices-certified data (a new and complex requirement).
- By now it was not about kava – it was a new process that could be applied to deny marketing authorisation

to any herbal or conventional medicine (without valid cause).

More than a decade passed before the decision could be contested in court – this could only happen once there was a finalised decision and as late as 2012 BfArM had not done this. A finalised decision was achieved after legal pressure, and then seven companies pursued the case against BfArM. The major arguments they presented were:

- Kava is efficacious against stress-related anxiety and is scientifically accepted in this indication.
- The number of hepatotoxicity case reports showing a certain degree of causality by kava is very small (n = 3), and absolutely insignificant when compared to the exposure figures (i.e. number of estimated daily doses taken across Germany). The observed risk does not justify the extreme measure of a ban.
- The therapeutic alternatives proposed by BfArM in every decision and expert statement, namely the benzodiazepines, cannot be regarded as safer remedies. With all proposed conventional pharmaceutical drug alternatives (e.g. benzodiazepines) the risk for the patient will be increased by renouncing kava use.

The court endorsed these arguments, and interestingly it did not even accept the alleged risk as proposed by BfArM. It considered the presentation of the risk of kava as a mere collection of assumptions and hypotheses that should have been substantiated by the presentation of scientifically sound data. The risk of hepatotoxicity was even considered minor, rated as "rare" or "very rare" and a pattern of toxicity could not be established from the available data.

Although Australian practitioners have had access to specified kava products, it is good to see this questionable decision overturned.

Acknowledgement

Mathias Schmidt worked with MediHerb staff, namely Kerry Bone, myself and Janice McMillan on the 119-page submission to the TGA prepared in November 2002.

Key Points at a Glance

- The decision by the German Health Authority (BfArM) to "ban" kava products was overturned by a German administrative court in June 2014.
- Among other findings, the court did not accept the alleged risk of kava as proposed by BfArM.
- The process that resulted in the ban did not appear to be solely about a reputed safety risk of kava, but was related to potentially denying the marketing authorisation of herbal products in Germany, with potential flow-on effects to other countries including Australia.
- BfArM has appealed the court's decision.

REFERENCES

- Schmidt M. German Court Ruling Reverses Kava Ban; German Regulatory Authority Appeals Decision. HerbalEGram: Volume 11, Issue 7, July 2014. Available from http://cms.herbalgram.org/heg/volume11/07July/GermanKavaBanReversal.html?ts=1421625709&signature=6fd807dbeb58b69bc6d9e1815218011e. Accessed January 2015. Also published in HerbalGram Issue 103, 2017, pp 38-43.
- Kraft K. Verwaltungsgericht Köln kippt das Kava-Verbot. *Z Phytother* 2014; **35**(4): 186-189
- Schmidt M, Morgan M, Bone K, McMillan J. Kava: A Risk-Benefit Assessment. In: Mills S, Bone K (eds). *The Essential Guide to Herbal Safety*. Elsevier Churchill Livingstone, St Louis, 2005, pp 155-221.