

STATES OF JERSEY



DRAFT ACT ANNULING THE MEDICINES (KAVA-KAVA) (PROHIBITION) (JERSEY) ORDER 2003 (P.69/2003): COMMENTS

Presented to the States on 17th June 2003
by the Health and Social Services Committee

STATES GREFFE

COMMENTS

1.0 Introduction

The Health and Social Services Committee (the Committee) made this Order on the recommendation of the Island's Medicines Advisory Council (the Council) which is established under the Medicines Law to provide advice to the Committee on matters relating to the execution of the Law and, in particular, on matters relating to the safety, quality or efficacy of medicinal products.

The Council is composed largely of health-care professionals with a lay Chairman. It takes note of decisions taken in other jurisdictions, and of the evidence leading to these decisions, in making recommendations to the Committee. Its principal aim, shared by the Committee, is to ensure that the public has reasonable access to medicines which have been demonstrated to be safe and effective, and to protect public health.

2.0 The Proposition

The report accompanying the proposition to annul the prohibition Order makes a number of assertions about the beneficial properties of Kava-kava. These, however, are difficult to substantiate as there appear to have been few, if any, well controlled and independently conducted clinical trials with Kava and the majority of claims made for it seem to be based on anecdotal accounts of its benefits.

On the other hand, and of particular and increasing concern to Health Care Authorities throughout the world, there is emerging evidence of the consumption of Kava being associated with liver damage. The report acknowledges this concern but suggests that these fears can be dismissed following work carried out at the Fiji School of Medicine. It would of course be in the interests of the Fijian Community to absolve Kava-kava from a causal relationship with toxicity.

The facts are that, since 1997, (when the routine monitoring of herbal medicines started) 70 world-wide cases of liver toxicity, possibly associated with the use of Kava-Kava, have been reported, resulting in 4 deaths and 7 liver transplants. There have been 4 reports of liver toxicity in the U.K. which have been associated with the consumption of Kava-Kava.

The Report asserts that "the huge weight of all the current evidence clearly indicates that moderate consumption of Kava is completely harmless, with no known side-effects and a number of medicinally beneficial features".

Emerging evidence (as opposed to claims unsupported by clinical or scientific appraisal) suggest that this may not be the case. On the basis of available evidence, the Committee on Safety of Medicines – a world-wide renowned body and independent of Government – has reached the view that the possible therapeutic benefits of Kava-Kava cannot at present be considered to outweigh its safety risks.

The report draws a comparison between Kava and alcohol in their ability to cause liver damage. It has been noted by the Committee on Safety of Medicines however that unlike alcohol, there is no evidence from reported cases of a 'safe' level of Kava consumption below which it is unlikely to cause toxicity. It is a difficulty of assessing both the safety and benefits of products containing Kava that they appear to vary in their "potency", because of the variety of methods used in its preparation. This variation, which may have a bearing on its unpredictability of effect, has been an important consideration in decisions taken in many jurisdictions to withdraw products containing Kava-kava from medicines markets.

3.0 Conclusions

U.K. Health Authorities have banned the use of Kava-Kava in unlicensed medicines. Similar action has been taken throughout the European Union (including Germany, quoted in the Report as supporting the use of Kava-Kava for certain conditions – though this was prior to the present concerns). The liver toxicity associated with its use seems to be rare, but unpredictable. There are no known measures which might be taken by individuals to reduce the risk or severity of liver reactions.

Against this background, and nothing to do with the herb's supposed 'euphoric' effect, it is considered that it would be irresponsible to take no action, and the Committee is persuaded that it is in the best interests of the community to withdraw any unlicensed medicinal product which contains Kava-Kava at present. This measure is not unique – there have been several cases where 'conventional' as well as herbal medicines have been withdrawn from the market when evidence of harmful effects has emerged.

The U.K. Medicines Control Agency has indicated that it will be undertaking a specific review in 2 years' time to assess whether the ban remains justified. The Island's Medicines Advisory Council will consider any new evidence which may emerge from that process in the formulating of any further advice to the Committee.

The Health and Social Services Committee does not believe that the substance contained in the Report accompanying the Proposition provides sound reasoning to differ from the view reached by the Committee on Safety of Medicines and accordingly opposes the proposed Annulment of the Medicines (Kava-Kava) (Prohibition) (Jersey) Order 2003.

KAVA-KAVA – further notes

1. Assessment of impact of prohibition

The impact of a prohibition locally is considered to be minimal. Firstly, consumption in the Island is thought to be very small (as the Report states “the fact is that very few people in Jersey have ever heard of it” [Kava-Kava]), and in effect it has largely been removed from the market for the past year as a result of a voluntary withdrawal by the herbal sector.

Additionally there are a number of alternative herbal remedies which have been traditionally used to relieve stress and which do not carry a risk of liver toxicity. These include products containing Valerian, Hops, Passiflora and Wild Lettuce.

In the longer term, the level of protection provided by the Prohibition Order may help to maintain a higher level of public confidence in herbal medicines than would be the case if continuing sales resulted in further reports of liver toxicity.

2. Assessment of reported cases

The 70 reported cases of liver damage have been or are being assessed for a causal relationship with Kava-Kava.

In 15 patients it is probable that Kava-Kava caused the liver toxicity.

In 30 cases it is possible that consumption of Kava-Kava was the cause.

In 5 patients it is unlikely that Kava-Kava was implicated.

19 cases were un-assessable and one is still being assessed.

3. Medicines Advisory Council

The Council’s membership is –

Medical Officer of Health
Representative of the Jersey Medical Society
Official Analyst
Chief Pharmacist
States Veterinary Officer
Representative of Employment and Social Security
Community Pharmacist
Member of Health and Social Services Committee (Chair)