

Pilot program to ease restrictions on the importation of kava for personal use

Consultation paper

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### Introduction

On 16 January 2019 during an official visit to Vanuatu, the Prime Minister, the Honourable Scott Morrison MP, <u>announced</u> that the Australian Government would work to develop a pilot program to ease some of the limitations on importation of kava into Australia for personal use. This initiative is part of the broader Australian Government Pacific step up, and recognises the cultural and economic importance of kava to Pacific Islanders.

In response to the Prime Minister's announcement, the Australian Government Department of Health's Office of Drug Control (ODC), responsible for regulating the import and export of drugs, is coordinating a proposal for a pilot program to commence in 2019.

### This consultation

The Australian Government is exploring the appropriate mechanism to increase the quantity of kava that may be imported into Australia by incoming passengers for personal use.

#### The focus of this paper is to seek your feedback on:

- a proposal to increase the quantity of kava that may be imported for personal use to 4 kilograms.
- any impact increasing the quantity of kava imported for personal use may have on the community?
- the approach to evaluate the pilot program, including health, social harms and feedback on the program.
- the duration of pilot program.

The ODC has issued this consultation paper as part of the Government's ongoing engagement with the Pacific and Pacific Islander communities in Australia and recognising that the use of kava transcends to other communities, including Aboriginal communities in certain parts of Australia.

# Background

### What is Kava?

Kava (also known as kava kava or *Piper methysticum*) is a member of the pepper family, which contains the psychoactive ingredient kavalactones, and has traditionally been cultivated by Pacific Islanders. Kavalactones are the psychoactive ingredient of kava. The root of the kava plant is usually either ground or chewed up and mixed with water or coconut milk to form a traditional beverage. Nowadays, some value added processing is done in Pacific Island Countries to produce kava supplement drinks and kava capsules, but it is generally exported as powdered product made up of dried roots.

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### **Kava Importation**

Kava is scheduled as a drug under the <u>Customs (Prohibited Imports) Regulations 1956</u> (PI Regulations) and requires permission from the ODC to import into Australia.

In 1997, a gazette notice was published under the PI Regulations that imposed a restriction on the quantity of kava, either in the root or dried form, which an incoming passenger aged 18 years or more could import into Australia in their accompanied baggage, without the need for a permit. The limit imposed was, and remains, 2 kilograms. However states and territories may impose their own controls that may prevent travellers bringing kava into their jurisdictions.

While imports for commercial purposes, for developing medicinal products are permitted, the ODC ceased issuing permits to import kava in 2007 for non-medical purposes, in response to concerns that the abuse of kava was contributing to negative health and social outcomes in some Aboriginal communities.

# Poisons Standard

Kava is a prescription only medicine except when included on the <u>Australian Register of Therapeutic Goods (ARTG)</u> in preparations:

- a) for oral use when present in tablet, capsule or teabag form that is labelled with a recommended maximum daily dose of 250 mg or less of kavalactones and:
  - i) the tablet or capsule form contains 125 mg or less of kavalactones per tablet or capsule; or
  - ii) the amount of dried whole or peeled rhizome and/or root in the teabag does not exceed 3 g;
  - and, where containing more than 25 mg of kavalactones per dose, compliant with the requirements of the Required Advisory Statements for Medicine Labels;
- b) in topical preparations for use on the rectum, vagina or throat containing dried whole or peeled rhizome and/or root or containing aqueous dispersions or aqueous extracts of whole or peeled rhizome and/or root; or
- c) in dermal preparations.

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# Listed medicine ingredient

Kava may be included as an ingredient in a medicine listed on the ARTG in accordance with the following specific requirements as listed in the <u>Therapeutic Goods (Permissible Ingredients)</u> <u>Determination (No. 4) 2018.</u>

#### Specific requirements applying to Piper methysticum (Kava)

- Kavalactones (of Piper methysticum) is a mandatory component of Piper methysticum.
- Only for oral use when the dosage form is 'tablet' or 'capsule'; or when the container type is 'tea bag'.
- When used in oral medicines, the maximum daily dose of kavalactones (of *Piper methysticum*) must be no more than 250 mg.
- If the dosage form is tablet or capsule then the quantity of kavalactones (of *Piper methysticum*) must be no more than 125 mg per tablet or capsule.
- Oral medicines containing more than 25 mg of kavalactones (of *Piper methysticum*) per dose require the following warning statement on the medicine label: - (PIPER) 'Not for prolonged use. If symptoms persist - seek advice from a healthcare practitioner. Not recommended for pregnant or lactating women (or words to that effect). May harm the liver'.
- The plant part must be root or rhizome.
- When for oral use, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome.
- When for topical use on the rectum, vagina or throat, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome.
- When the container type is tea bag the maximum quantity per tea bag must be no more than 3 grams of dried whole or peeled root or rhizomes.

### Food

Under the <u>Australian New Zealand Food Standards Code for kava</u>, kava may not be sold, or include any substance derived from kava unless it is:

- a) a beverage obtained by the aqueous suspension of kava root using cold water only, and not using any organic solvent; or
- b) dried or raw kava root.

### Current commercial importation

The ODC can grant import permits for kava under the PI Regulations for the following purposes:

- a) A finished product on the ARTG.
- b) Kava raw material:
  - to manufacture a finished product included on the ARTG through a licensed manufacturer
  - ii) for scientific purposes.

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# Proposed pilot program

The aim of the pilot is to trial easing the current restrictions on the importation of kava into Australia for personal use.

# **Proposal**

The Australian Government is proposing to increase the quantity of dried kava root or dried product that may be imported into Australia by incoming passengers for personal use (without the need for a medical prescription or import permission from the ODC) from 2 kilograms to 4 kilograms.

This may be achieved via a legislative instrument. The PI Regulations would be amended to allow a legislative instrument to include quantity, use, age and period of effect.

Pursuant to the regulation amendment, a legislative instrument could be issued that would stipulate that 4 kilograms of dried kava, in either root or product form, could be imported for personal use, by people aged 18 years or more.

The effectiveness of the pilot program will be assessed two years after the commencement of the proposed legislative instrument, after which a report on the outcome of the pilot will be provided to the Australian Government. Feedback from interested parties will also be considered as part of the evaluation of the pilot.

### **Effect**

With the exception of an increased import threshold, border controls in relation to kava would remain unchanged.

State and territory jurisdictions would maintain authority for kava controls within their borders with no consequential amendments proposed for the regulation of kava. For example a jurisdiction might limit the use of kava or quantities that may be possessed irrespective of border controls.

The scheduling of kava in the <u>Poisons Standard</u> and the <u>Australian New Zealand Food Standards</u> <u>Code for kava</u> would both remain unchanged. The pilot program will work in concert with the broader aspects of current kava regulation in Australia.

# Understanding the use of kava in Australia

### Use

The traditional patterns of use of kava in Australia are observed in ceremonial, religious and cultural settings among Pacific Islander communities. Extent of use is variable but is primarily used during a kava ceremony several occasions per year and tends to include the consumption of small amounts of kava over a brief period of time.

Among Aboriginal communities, use is generally limited to several communities in Arnhem Land. With the enforcement of import restrictions in 2007, kava is generally consumed in small groups.

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# Health impacts of kava use

There is limited evidence that low or moderate use of kava has adverse health consequences; noting that the frequency of consumption and quantity consumed per person does vary and the potential for alcohol and drug interactions.

However, liver toxicity is a known adverse effect with kava if consumed in high dosages and frequency, and the quality of kava is compromised. Elevated liver enzymes on exposure return to normal levels upon ceasing or reducing kava consumption. Long term consumption of kava can lead to toxic effects, such as dry and scaly skin which is reversible on cessation.

#### Additional information:

Scheduling of Medicines and Poisons/Scheduling Delegates final decisions, July 2016: <u>Piper methysticum (kava)</u>

Food and Agriculture Organization of the United Nations, World Health Organisation Report: Kava: a review of the safety of traditional and recreational beverage consumption

### Social impacts of kava use

Social and health impacts are an important consideration. While we know that there are illicit markets operating in certain communities, we cannot establish how much, if any, illicit kava has been diverted from passengers importing 2 kilograms under the current permissible threshold. In addition, the Commonwealth does not maintain records of total quantities of kava products brought into Australia under the current personal importation scheme.

The kava using community has identified kava use as a socially valued and culturally significant activity that may promote fellowship and companionship. Kava clubs provide opportunities to learn about and maintain culture in an environment where participants feel accepted.

Understanding what levels of use may create harmful consequences is difficult for the kava using community to identify; however, there is evidence to suggest that the time spent in activities related to kava use by regular kava drinkers among Pacific Islanders could create relationship distress.

The consequences of kava use are understood by the kava using community in the context of alcohol related harms experienced in many communities; though kava is viewed as being less harmful than alcohol.

Leaders within Aboriginal communities have expressed public concern about the impact kava has on both individuals and the community. This is supported by evidence to suggest that illicit market activity in Arnhem Land has negative financial impacts on communities.

#### Illicit kava

Data related to seizures of kava at the border and within state and territory jurisdictions highlights the many forms that kava is present in Australia and Pacific Island Countries.

There are challenges in determining the origin of kava in illicit markets. We know from the seizure data that there is an illicit market, and we know that there are myriad lawful options for the domestic possession of kava including via prescription, in ARTG listed products, domestic cultivation and personal import.

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What is difficult to determine is how much of the illicit market, if any, is attributed to the diversion of kava from passengers lawfully importing 2 kilograms under the current regulatory framework. Consequently, it is difficult to forecast the impact that an increase to the quantity of kava imported for personal use may have on the illicit market and the communities where this market operates.

### Commercialisation

The Australia Government is involved in a number of initiatives that support the production of kava for commercial purposes, including the Market Development Facility and the Pacific Horticultural and Agricultural Market Access Program (PHAMA). PHAMA provides practical and targeted assistance to help Pacific Island Countries manage regulatory aspects associated with exporting primary and value added products to export markets around the world.

We are aware that the Prime Minister's announcement will introduce debate about easing of restrictions around commercial importation of kava. The Prime Minister's announcement focuses solely on the personal importation of kava; therefore, the importation of kava for a commercial purpose is not being considered in this proposal.

### Your feedback

Are you a kava user, Pacific Islander or Indigenous community leader, health specialist, government, law enforcement or other interested party?

We seek your views on the proposed regulatory changes that would facilitate the introduction of a pilot program to ease the restrictions on the importation of kava for personal use. Your input will assist us to address any unintended consequences and to better inform the proposal.

# Issues to consider in your submission

#### General



- Is an increase to 4 kilograms of kava a suitable quantity for personal use?
- What are the health and social impacts of the proposal to increase the amount of kava that may be imported for personal use?
- Is two years a sufficient period for the pilot?
- What methods of evaluation should apply to this pilot?

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# How to submit

Complete the consultation submission coversheet and attach to an email with your submissions, in either pdf or word format, and email to <a href="mailto:dcs@health.gov.au">dcs@health.gov.au</a> with the title KAVA-Submission.

Alternatively, hardcopy submissions with a printed coversheet may be mailed to:

Office of Drug Control Department of Health GPO Box 9848 Canberra ACT 2601

This consultation closes on 22 March 2019.

# **Enquiries**

If you have any questions relating to submissions please direct them to: <a href="mailto:dcs@health.gov.au">dcs@health.gov.au</a>.

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# Version control

Updates to this document will occur automatically on the Office of Drug Control website and the revision table below will list the amendments as they are approved.

Date	Version	Amendments	Approved by
22 February 2019	1.0	Original publication	ODC

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