

Legislative Assembly for the
Australian Capital Territory

Medicines, Poisons and Therapeutic Goods
(Kava Exemption) Amendment Regulation 2013 (No 1)

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Explanatory Statement

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Overview

The *Medicines, Poisons and Therapeutic Goods Act 2008* (the MPTG Act) adopts the Standard for the Uniform Scheduling of Medicines and Poisons (the SUSMP). The MPTG Act refers to this as the 'medicines and poisons standard'.

The objective of the MPTG Act is to promote and protect public health and safety by minimising medicinal misadventure with, and diversion of, regulated substances, and the manufacture of regulated substances that are subject to abuse. The MPTG Act also has the purpose of ensuring that consumers of prescription and non-prescription medicines have adequate information to allow them to use medicines safely and effectively. The MPTG Act outlines a range of offences relating to dealings with regulated substances according to their listing in the SUSMP.

The MPTG Act provides under section 190 that a regulation may exempt a person, regulated thing, premises or dealing with a regulated thing, or anything else from the operation of the MPTG Act. A regulation may also authorise the Minister to issue an exemption. This power was included as there are circumstances where it may be appropriate for regulatory or policy reasons that an exemption be given. The MPTG Act provides a safeguard by requiring an exemption to be public knowledge.

Piper Methysticum (kava) is listed as a prescription-only substance under Schedule 4 of the SUSMP with corresponding restrictions under the MPTG Act. As such, its possession and use is illegal if there is no valid prescription.

This Regulation amends the Medicines, Poisons and Therapeutic Goods Regulation 2008 (the MPTG Regulation) to insert a new section; section 864. The new section exempts the cultural use of kava at public events declared by the Minister by notifiable instrument, and subject to any conditions imposed in the declaration.

This Regulation recognises the role that kava plays in Pacific island culture, and through the application of the exemption enables those cultures and their customs to be performed and showcased at applicable public events.

DETAILS

A detailed explanation of each clause of the Regulation follows.

Clauses

Clause 1 Name of Regulation

The first clause of the Regulation declares the name of the Regulation to be the Medicines, Poisons and Therapeutic Goods (Kava Exemption) Amendment Regulation 2013 (No 1).

Clause 2 Commencement

Pursuant to this provision, the Regulation is to commence on the day after notification.

Due to the operation of section 75(1) of the *Legislation Act 2001* (the Legislation Act) the naming and commencement provisions of this Regulation, clauses 1 and 2, commence automatically on the day the Regulation is notified. A note to that effect is included in the provision.

Clause 3 Legislation amended

This provision alerts the reader that this Regulation amends the MPTG Regulation.

Upon commencement this Regulation will alter the MPTG Regulation in accordance with the provisions that this Regulation contains. This Regulation will then be immediately repealed.

Consequentially, from the date that this Regulation commences a new republication of the MPTG Regulation will be available. That new republication will feature the alterations made by this Regulation.

Clause 4 New section 864

Section 190(1) (a) of the MPTG Act permits the MPTG Regulation to make exemptions from the operation of the MPTG Act. Exemptions can concern persons, premises, dealings, or regulated substances. Utilising this power, clause 4 inserts into the MPTG Regulation a new provision, section 864, exempting kava from the prescription only requirements of the MPTG Act. The exemption will allow certain forms of dealing with kava at declared public events, provided that the dealing is in accordance with the customs of the Pacific islands.

Using the rhizome of the *Piper Methysticum* plant, an aqueous dispersion or extract can be prepared, which when consumed orally can have a sedative, anxiolytic or anaesthetic like effect. Both the plant and the concoction made from its rhizome are commonly referred to as kava. The potential adverse effects from consumption of kava, including liver toxicity from medicinal formulations and the potential for adverse health and social effects due to abuse and misuse of kava, are key reasons why it has been listed as a prescription-only substance under Schedule 4 of the SUSMP. Schedule 4 of the SUSMP is automatically adopted under the MPTG Act with corresponding restrictions. As such, the possession and use of kava is illegal if there is no valid prescription.

The first subsection in section 864 exempts kava in four forms.

Using powder made from the dried rhizome of the kava plant, an aqueous dispersion or aqueous extract of kava can be prepared. Preparations of kava in this form, if for oral use by humans, are exempted by virtue of subsection 1(d).

An aqueous dispersion or extract can also be prepared using either both raw or dried rhizome, which can be whole or peeled. Preparations of kava in this form are also exempted by subsection 1(c), again provided that the preparation is for oral use by humans.

It would be illogical and impractical to exempt aqueous dispersions or extracts containing raw or dried rhizome, or a powder made from dried rhizome, without authorising the possession of the rhizome from which the preparation is to be made. To that end, subsection 1(a) exempts raw and dried rhizome, whether whole or peeled, and subsection 1(b) exempts powder made from dried rhizome, provided in both cases that it is for use in an aqueous dispersion or extract which is intended to be consumed by humans.

The exemptions created in subsection 1 are not absolute. For the exemptions to operate, two critical requirements set out in subsection 2 must be met. The first requirement is that the kava be prepared, possessed and consumed in accordance with the customs of the Pacific islands.

A number of nations and states that make up the Pacific islands are known to prepare and consume kava, including Fiji, Samoa, Tonga, Vanuatu, New Guinea and Hawaii. There are slight variations in the recognised customs of Pacific islands surrounding kava preparation and consumption. Nevertheless, in most customs the kava is prepared and consumed, or both as part of kava ceremony. This will often involve a gathering of people, in many instances in a 'kava circle', and the kava being served or drunk from a traditional 'kava bowl'.

Accordingly, for the exemption to apply the kava usage must be consistent with recognised customs of a Pacific island nation. This is reflective of the fact that the exemption is more about enabling a celebration of the culture and customs of Pacific island peoples than about permitting kava preparation and consumption.

The other critical requirement for the exemption to operate is that the kava is prepared, possessed and consumed in connection with an event declared by the Minister. Such a declaration is, by virtue of subsection 5, a notifiable instrument. The Legislation Act sets out what constitutes a notifiable instrument, and requires that notifiable instruments be notified on the ACT Legislation Register website.

Under subsection 3 the Minister may only declare public events, such as the National Multicultural Festival. It is important that this provision be interpreted applying the ordinary common meaning of 'public event'. It must be open to the community at large. The exemption cannot be applied to permit the preparation and consumption of kava at private events, such as birthdays and weddings.

In declaring a public event to which the exemption will apply, the Minister may impose any condition on the event or the usage of kava that the Minister considers appropriate. Some public events, such as the National Multicultural Festival, run over several days, extend into the evenings, and can take place over a large area. The ability of the Minister under subsection 4 to impose conditions recognises that it may be necessary to limit the exemption to a single day of an event, or during certain hours of an event. It is also common for some public events to take place at multiple locations. Where this is the case, a condition can be imposed that would specify at which site or sites the exemption will apply.

It may also be necessary to require signage for the event. This may be to alert the public about the operation of other conditions, such as approved times and locations. It is also important to recognise that it is unlikely that every person attending a public event will be familiar with kava and its effects. It would therefore be reasonable for the Minister to require that signs or information be available alerting the public to the effects of kava consumption, and offering cautionary warnings such as the importance of not operating a motor vehicle following consumption of kava.

The conditions specified in paragraphs (a) to (e) of subsection 4 are not an exhaustive list of conditions that may be imposed, but should rather be regarded as conditions that are most likely to be imposed for most declared events. Paragraph (f) contemplates that other conditions may be imposed, which may be a standard condition imposed on all declared events, or conditions specific to an event or a point in time.

An example of a condition not listed in the subsection that is likely to be commonly imposed would be a condition effectively prohibiting kava from being sold, including in exchange for a 'donation' or as part of a fundraising activity. The Minister may regard it as inappropriate for persons to sell kava at a public event, thereby profiting from the exemption given. The Minister may also regard that the sale of kava is inconsistent with the intent of an exemption for cultural purposes, as it may encourage excessive or non-cultural use. The imposition of a condition preventing sale of kava would put the matter beyond doubt, and would ensure an exemption created to enable the celebration of Pacific island culture is not abused for profit or financial gain.

The importation of kava is restricted by Commonwealth Customs legislation. Kava may only be imported for medical and/or scientific purposes and only under a *Licence to Import Controlled Substances* and an import permit. Nevertheless, there is an exemption to the requirements of the Australian Customs Service that allows an incoming passenger on a ship or aircraft to bring kava to Australia without an import permit if:

- the incoming passenger is aged 18 years or over;
- the kava is in either root or dried powder form;
- the amount of kava does not exceed 2 kilograms; and
- the kava is carried in the passenger's accompanied baggage.

It is intended that the use of kava in relation to this exemption be consistent with Commonwealth importation restrictions.

It should be noted that as the Minister's authority does not extend beyond the Australian Capital Territory the Minister cannot declare an event occurring outside the Territory to be a public event. This, by extension, will prevent kava from being prepared or consumed outside of the Territory, or for persons to possess or supply kava outside of the ACT.

Similarly, many Commonwealth agencies are not bound by the MPTG Act. Should a Commonwealth agency be considering organising a public event at which they would like kava to be prepared and consumed, that agency will need to obtain its own legal advice as to whether it is subject to the MPTG Act.

Finally it is important to emphasise that nothing in the exemption is meant to encourage the use of kava as part of daily living. Kava is otherwise only permitted in preparations on prescription by a doctor. Restricting the application of the exemption to declared public events has been done not just to prevent the day to day use of kava, but to also ensure that the exemption can be applied only for events of special importance to the ACT community.