Legislative Assembly for the Australian Capital Territory

Medicines, Poisons and Therapeutic Goods

Amendment Regulation 2012 (No 1)

SL2012-5

Explanatory Statement

Circulated by the authority of Katy Gallagher MLA Minister for Health

February 2012

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2012 (No 1)

Overview

The *Medicines, Poisons and Therapeutic Goods Act 2008* consolidated four Acts and their regulations regarding ACT law on medicines, poisons and prohibited substances; by repealing and replacing the *Poisons and Drugs Act 1978*, the *Poisons Act 1933*, the *Public Health (Prohibited Drugs) Act 1957*, and significantly amending the *Drugs of Dependence Act 1989*. The Act adopts the Standard for the Uniform Scheduling of Medicines and Poisons (the SUSMP). Note the Act refers to this as the medicines and poisons standard.

The objective of the Act is to promote and protect public health and safety by minimising medicinal misadventure with and diversion of regulated substances, accidental or deliberate poisonings and the manufacture of regulated substances that are subject to abuse. The 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 Act outlines a range of offences relating to dealings with regulated substances according to their listing in the SUSMP.

The 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 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 may be required to be given. The Act provides a safeguard by requiring an exemption to be public knowledge.

This regulation proposes to amend the Medicines, Poisons and Therapeutic Goods Regulation 2008 to insert a new section (section 864) for an exemption related to Piper Methysticum (kava). Piper Methysticum (kava) is listed as a prescription-only substance under Schedule 4 of the SUMP with corresponding restrictions under the Act. As such, its possession and use is illegal if there is no valid prescription.

An exemption is being provided for a trial during the 2012 National Multicultural Festival. The trial is in recognition of the role that Piper Methysticum (kava) plays in Pacific Islander culture. For the purposes of the trial, an exemption will allow for the preparation, possession and use of Piper Methysticum (kava) according to cultural practices of the Pacific Islands for the duration of the 2012 National Multicultural Festival.

Clauses

Clause 1 provides for the name of the regulation as the Medicines, Poisons and Therapeutic Goods Amendment Regulation 2012 (No 1).

Clause 2 provides that the regulation commences on the day after its notification day.

Clause 3 provides that the legislation that is amended by the regulation is the Medicines, Poisons and Therapeutic Goods Regulation 2008.

Clause 4 inserts a new section 864. The section provides for an exemption under section 190(1)(a) of the Act.

Schedule 4 of the SUSMP provides that Piper Methysiticum (kava) is restricted in preparations for human use except when included on the Australian Register of Therapeutics Goods in certain preparations. An exemption is being provided to allow for Piper Methysticum (kava) preparations to be consumed at the National Multicultural Festival.

The preparations that are exempt from the Act are the dried whole or peeled rhizome or preparation for oral use containing aqueous dispersions of aqueous extract of the whole of peeled rhizome. The exemption applies only if the preparations are prepared, possessed and used in accordance with the customs of the Pacific Islands and consumed in connection with the National Multicultural Festival. The National Multicultural Festival is between 10 February 2012 and 12 February 2012 in Garema Place, Petrie Plaza, City Walk, Civic Square, Ainslie Place and Akuna Street. The section is expired on 12 February 2012 at midnight.