Health (Drugs and Poisons) Amendment Regulation (No. 2) 2016

Explanatory notes for SL 2016 No. 67

made under the

Health Act 1937

General Outline

Short title

Health (Drugs and Poisons) Amendment Regulation (No. 2) 2016

Authorising law

Section 180 of the *Health Act 1937*

Policy objectives and the reasons for them

The broad policy objective of the *Health (Drugs and Poisons) Amendment Regulation (No. 2) 2016* (the amendment regulation) is to provide an interim framework for regulated access to medicinal cannabis.

Access to medicinal cannabis, and its use for therapeutic purposes, is jointly regulated by Commonwealth and state/territory laws. The *Commonwealth Poisons Standard 2015*, also known as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), schedules cannabis and cannabis-derived products according to the level of regulatory control required to protect public health and safety. This scheduling scheme is administered by the Therapeutic Goods Administration (TGA).

Under the SUSMP, schedule 9 (S9) substances are classified as 'poisons', because of their toxicity and potential for abuse. The use of S9 substances is generally prohibited. Any cannabis or cannabis-derived product is automatically scheduled S9, unless it is otherwise scheduled. In Queensland, all scheduled substances are regulated under the *Health (Drugs and Poisons) Regulation 1996* (HDPR).

The TGA is proposing to re-schedule certain cannabis and cannabis-derived products. On 5 April 2016, the TGA released an interim decision, proposing all botanical cannabis products and botanically-derived cannabis extracts, when prepared and packed for therapeutic use, be re-scheduled from S9 poisons to S8 controlled drugs ('medicines'). Synthetic cannabis products and cannabis plants prior to being harvested are excluded from the re-scheduling,

and will remain S9 substances. The expected implementation date for the TGA re-scheduling decision is 1 June 2016.

Re-scheduling alone will not enable these newly re-scheduled S8 medicinal cannabis products to be used in Queensland, and therefore complementary amendments to relevant Queensland legislation are required.

As noted above, the HDPR is the applicable Queensland legislation. However in future, it is proposed to regulate medicinal cannabis products in Queensland under a standalone Act. To this end, the Public Health (Medicinal Cannabis) Bill 2016 (the Bill) was recently introduced into the Queensland Parliament.

The Bill creates a regulatory framework to facilitate treatment with medicinal cannabis, while preventing its unauthorised use. Subject to its enactment, this framework will replace those provisions in the HDPR which would otherwise apply to medicinal cannabis products, regardless of their classification.

However, the Bill will not be debated until the second half of 2016. Therefore, to ensure Queensland patients can take immediate advantage of the re-scheduling decision when implemented, amendments to the HDPR are proposed as an interim measure until the Bill is enacted.

Achievement of policy objectives

The Bill provides two pathways for patients to obtain treatment with medicinal cannabis. The patient-class prescriber pathway gives specialist medical practitioners an as-of-right authority to use medicinal cannabis to treat particular classes of patient, and the single-patient prescriber pathway allows other medical practitioners to apply on a case-by-case basis to use medicinal cannabis to treat a specific patient.

The amendment regulation inserts a new part into the HDPR, to provide two pathways for patients to obtain treatment with medicinal cannabis that mirror those pathways in the Bill. This new part sits within the existing provisions regulating S8 controlled drugs, and as S8 medicinal cannabis products are then defined as an a new category of controlled drugs, the existing regulatory framework for S8 substances automatically apply to support the new treatment pathways. However, to ensure the necessary controls in the Bill in relation to medicinal cannabis also apply to these pathways, the new part excludes certain existing provisions from applying to medicinal cannabis, and then inserts corresponding new provisions replicating those controls in the Bill.

Given the Bill is a standalone piece of legislation and the new part inserted into the HDPR by the amendment regulation must fit within an existing regulatory framework, the pathways and related controls in the Bill that have been replicated by the new part have been slightly modified from how they appear in the Bill in order to operate effectively within the HDPR. However, these changes, such as not including the Bill requirement for pharmacists to obtain a dispensing approval from the chief executive, are acceptable compromises in what is only an interim framework, and do not impose limitations on a patient's ability to access treatment.

Under the patient-class prescriber pathway, specialists in paediatric neurology, oncology and palliative care medicine have an as-of-right authority to prescribe medicinal cannabis products to patients within their care, without the need to obtain any further state approval.

Under the single-patient pathway, which can be used where a patient is ineligible to be treated by a patient-class prescriber, the patient's treating medical practitioner may make an application to the chief executive of Queensland Health for approval to treat the patient with medicinal cannabis. Applications made under the single-patient pathway will be considered on a case-by-case basis.

The amendment regulation also includes a sunset clause, so the new part will be repealed when the corresponding provisions of the Bill commence.

Consistency with policy objectives of authorising law

The amendment regulation is consistent with the policy objectives of the *Health Act 1937*.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Duplication will be avoided by repealing the new part when the corresponding provisions of the Bill commence.

Alternative ways of achieving policy objectives

The amendment regulation is the only means of achieving the policy objectives in the short term. The proposed Bill will achieve the policy objectives in the long term.

Benefits and costs of implementation

The amendment regulation will not impose any additional costs.

Consistency with fundamental legislative principles

The amendment regulation is consistent with fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*.

Consultation

The amendment regulation closely aligns with the regulatory framework in the proposed Bill, and the Bill has been subjected to extensive community and health industry consultation. Over one thousand people completed an online survey and of these, 96 per cent were in

favour of treatment with medicinal cannabis. Targeted consultation with key health industry stakeholders also showed strong support for the framework in the Bill, particularly the controls around who may prescribe, dispense and possess medicinal cannabis products.

Consultation with the Office of Best Practice Regulation (OBPR) was undertaken in compliance with the Regulatory Impact Statement (RIS) system. As extensive community and industry consultation on the proposed Bill was undertaken, OBPR considered the amendment regulation would be unlikely to benefit from further assessment under the Treasurer's RIS guidelines.

Notes on provisions

Clause 1 Short title

Clause 1 provides that the short title of the regulation will be the *Health (Drugs and Poisons) Amendment Regulation (No. 2) 2016*.

Clause 2 Commencement

Clause 2 provides that the regulation commences on 1 June 2016 to correspond with the implementation of the Commonwealth decision to re-schedule medicinal cannabis.

Clause 3 Regulation amended

Clause 3 provides that the regulation amends the *Health (Drugs and Poisons) Regulation 1996* (HDPR).

Clause 4 Insertion of new ch 2, pt 3A

Clause 4 inserts a new part into the HDPR to provide the interim framework for the management of medicinal cannabis in Queensland.

Inserted section 78B (Definitions for part) provides the definitions that are used throughout the part.

Inserted section 78C (Purpose of part) sets out the purpose of the part is to provide regulated access to medicinal cannabis through the prescription of medicinal cannabis under a system of case-by-case approvals (single-patient prescribers) or without approvals (patient-class prescribers). The part is only in force until the commencement of a proposed Bill which will then achieve this purpose.

Inserted section 78D (Application of part) clarifies that to the extent of any inconsistency, this part prevails over any other provision in the HDPR. It also specifically excludes certain sections in relation to medicinal cannabis. These excluded sections relate to endorsements for specific professions under the HDPR. Further, inserted subsection (3) clarifies that only a patient-class prescriber or single-patient prescriber can prescribe medicinal cannabis and that a person authorised to administer medicinal cannabis can only do so in accordance with a prescription written by one of these prescribers.

Inserted section 78E (Grant of medicinal cannabis approval) provides the power for the chief executive of Queensland Health to grant a medicinal cannabis approval to a doctor for the treatment of a particular patient with medicinal cannabis. The section clarifies that the approval is an endorsement under the HDPR.

Inserted section 78F (Patient-class prescribers) allows a patient-class prescriber, if satisfied a patient needs medicinal cannabis for treatment, to give a prescription for the issue or supply of medicinal cannabis for the purpose of treating the patient or to administer medicinal cannabis to the patient. The prescriber may also obtain and possess the medicinal cannabis until the patient can be treated and only for the purpose of treating the person. Further, the prescriber may supply or administer the medicinal cannabis to the patient, or issue the medicinal cannabis to the patient's carer. A patient-class prescriber is a specialist health practitioner in the fields of oncology, paediatric neurology or palliative care or a registrar in those fields working under the personal supervision of the practitioner.

Inserted section 78G (Single-patient prescribers) allows a single-patient prescriber, if satisfied a patient needs medicinal cannabis for treatment, to give prescription for the issue or supply of medicinal cannabis for the purpose of treating the patient or to administer medicinal cannabis to the patient. The prescriber may also obtain and possess the medicinal cannabis until the patient can be treated and only for the purpose of treating the person. Further, the prescriber may supply or administer the medicinal cannabis to the patient, or issue the medicinal cannabis to the patient's carer. A single-patient prescriber means a medical practitioner who is the holder a medicinal cannabis approval.

Inserted section 78H (Patients) allows a patient to obtain, possess or self-administer lawfully-prescribed medicinal cannabis. The patient can also issue medicinal cannabis to the doctor who prescribed it or to a carer.

Inserted section 78I (Pharmacists) allows a pharmacist to obtain and possess medicinal cannabis for the purpose of selling and supplying the medicinal cannabis to a patient or for selling or issuing the medicinal cannabis to a carer. The pharmacist is also authorised to sell or supply the medicinal cannabis to a patient or to sell or issue the medicinal cannabis to a carer. The pharmacist can only do these things under a prescription written by a patient-class prescriber or a single-patient prescriber.

Inserted section 78J (Carers) allows a carer of a patient to obtain and possess medicinal cannabis until the patient can be treated and only for the purpose of treating the patient. The carer is authorised to supply the medicinal cannabis to the patient so they can self-administer or if the patient cannot self-administer, the carer can administer the medicinal cannabis. The carer can also issue medicinal cannabis to a single-patient prescriber or patient-class prescriber so they can administer it to the patient. The carer can only do these things under a prescription written by a patient-class prescriber or a single-patient prescriber. A carer, for a patient, means an adult who has responsibility for the immediate care and safety of the patient.

Inserted section 78K (Clinical trials) provides the power for the chief executive of Queensland Health to grant a medicinal cannabis approval to a person for the purposes of an approved clinical trial. An approved clinical trial is defined in the HDPR to be a clinical trial or other use of medicinal cannabis solely for experimental purposes in humans approved by the Therapeutic Goods Administration or a human research ethics committee.

Inserted section 78L (Requirement for prescribers to notify chief executive) places an obligation on a patient-class prescriber or a single-patient prescriber to give the chief executive of Queensland Health written notification whenever they prescribe, supply, issue or administer medicinal cannabis. The notice must state the name, date of birth, medical condition and symptoms of the patient and also the pharmacy from where the medicinal cannabis will be dispensed.

Inserted section 78M (Conditions applying to prescribers) allows the chief executive of Queensland Health to impose conditions on a patient-class prescriber's or single-patient prescriber's dealings with medicinal cannabis. The section lists some examples of conditions such as requirements relating to the prescription, monitoring or reporting. A condition could also be that the prescriber needs to comply with a stated code, guideline, protocol or standard. For single-patient prescribers, the chief executive's powers to impose conditions are in

addition to the powers to impose conditions on endorsements (authorities, approvals, licences and permits) under chapter 1, part 5 of the HDPR.

Inserted section 78N (Requirement for pharmacists to notify chief executive) places an obligation on pharmacists give the chief executive of Queensland Health written notification within 24 hours whenever they dispense, sell, issue or supply medicinal cannabis. The notice must state the name, medical condition and symptoms of the patient and also the type of medicinal cannabis that was dispensed, sold, issued or supplied.

Inserted section 78O (Conditions applying to pharmacists) allows the chief executive to impose conditions on a pharmacist's dealings with medicinal cannabis. The section lists some examples of the conditions such as conditions relating to the storage and dispensing of the medicinal cannabis. A condition could also be that the pharmacists must comply with a stated code, guideline, protocol or standard.

Inserted section 78P (Expiry of part) sets the expiry of the inserted part to be the earlier of the commencement of the proposed Bill or 1 January 2017. As discussed above, it is proposed to repeal this part upon the commencement of the Bill which is anticipated for the second half of 2016.

Clause 5 Amendment of appendix 9 (Dictionary)

Clause 5 amends the definition of *approved clinical trial* to include that an approved clinical trial could also be a use of medicinal cannabis which is solely for experimental purposes in humans.