Health (Drugs and Poisons) Amendment Regulation (No. 3) 2016

Explanatory notes for SL No. (205) 2016

made under the

Health Act 1937

General Outline

Short title

Health (Drugs and Poisons) Amendment Regulation (No. 3) 2016

Authorising law

Section 180 of the *Health Act 1937*

Policy objectives and the reasons for them

The policy objective of the *Health (Drugs and Poisons) Amendment Regulation (No. 3) 2016* (the Amendment Regulation) is to amend the regulatory framework for medicinal cannabis and to restrict access to para-aminopropiophenone.

Queensland medicinal cannabis regulatory framework

The Commonwealth *Poisons Standard 2015*, also known as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), schedules substances (from Schedule 2 to Schedule 10) 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).

The *Health (Drugs and Poisons) Regulation 1996* (HDPR) prohibits any Schedule 9 (S9) poison (also known as a 'prohibited substance') being used for a therapeutic purpose.

In December 2015, section 270B was inserted into the HDPR to empower the chief executive to grant case-by-case approval for a doctor to prescribe an S9 poison that is a medicinal cannabis product. This type of approval is supported by the existing regulatory framework in the HDPR for the lawful use of other poisons. However, given S9 substances are dangerous and only allowed very narrow uses under the HDPR, this regulatory framework is limited in scope.

The new section 270B also empowered the chief executive to grant approval for an S9 poison that is a medicinal cannabis product to be used in an approved clinical trial.

The HDPR provides a much broader regulatory framework for the lawful use of Schedule 8 (S8) controlled drugs. In June 2016, part 3A was inserted into chapter 2 of the HDPR to provide a separate regulatory framework for the lawful use of a controlled drug that is a medicinal cannabis product. Under this framework, the chief executive may grant case-by-case approval for a doctor to prescribe a controlled drug medicinal cannabis product (the 'single-patient prescriber' pathway), and may also authorise a class of specialists to prescribe a controlled drug medicinal cannabis product without the need for an individual approval (the 'patient-class prescriber' pathway).

New part 3A also empowered the chief executive to grant approval for an S8 controlled drug that is a medicinal cannabis product to be used in an approved clinical trial.

This separate regulatory framework for controlled drug medicinal cannabis products is narrower than the framework for other S8 substances, given the generally unproven safety and efficacy profile of most medicinal cannabis products.

It should be noted that both medicinal cannabis regulatory frameworks in the HDPR are only interim measures, given the relevant provisions will repealed by the *Public Health (Medicinal Cannabis) Act 2016* (the Act) when it commences.

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. The TGA later confirmed this interim decision, with the final decision to be implemented on 1 November 2016. Synthetic cannabis products are excluded from the re-scheduling, and will remain S9 substances.

Synthetic S9 medicinal cannabis products are not available for patient treatment, and are unlikely to become available for this purpose in the near future. However, synthetic S9 medicinal cannabis products may have immediate applications in relation to clinical trials, pre-clinical trial research (e.g. animal testing) or analytical activities for scientific or compliance purposes (e.g. calibrating equipment used to determine THC (tetrahydrocannabinol) levels).

Given the pending re-scheduling, and the unlikelihood of any S9 medicinal cannabis products being used for patient treatment in the foreseeable future, it is unnecessary to continue the existing regulatory framework in the HDPR in relation to S9 medicinal cannabis.

Continuity of medicinal cannabis treatment during hospitalisation

As noted above, the medicinal cannabis products most likely to be used for individual patient treatment are S8 controlled drugs. Further to this, a policy issue has now arisen in relation to whether the interim regulatory framework in the HDPR for such products is sufficiently clear and flexible to ensure the continuity of treatment for a patient who has been lawfully prescribed and dispensed a medicinal cannabis product where the patient is admitted to hospital. The HDPR defines the term *hospital* to mean a public sector hospital or private hospital. Under the hospital-related medicinal cannabis provisions inserted by the Amendment Regulation, the definition of hospital is extended to include a hospice and a medical centre at a prison.

Once a patient is admitted, the treating team within the hospital, being the doctors, nurses and pharmacists, assume care of the patient, including the prescription and administration of any medicine required to treat the patient's medical condition.

In a hospital, directions for patient treatment take the form of a written instruction, being an entry on the patient's hospital medication chart, rather than a prescription. The decisions of the treating team supersede any standing treatment decision of the doctor authorised under the HDPR to treat the patient with a medicinal cannabis product, including any prescription given for the product.

It is also likely any medicine in the possession of the patient at the time of admission will be taken by hospital staff and secured in the hospital pharmacy for use by the patient as required. Accordingly, neither the patient nor their carer will be able to possess, supply, issue or administer the patient's medicinal cannabis product as needed and as authorised under sections 78H and 78J of the HDPR, respectively.

However, the treating team is not authorised under the regulatory frameworks in the HDPR for S8 medicinal cannabis products to fully perform the regulated activities required to enable the patient's continued treatment with their medicinal cannabis product while hospitalised.

Enrolled nurses and registered nurses are both authorised, under section 58A and 67 of the HDPR, respectively, to possess a controlled drug and administer a controlled drug on the written instruction of a doctor. A registered nurse may also perform these activities on an oral instruction, although section 97 of the HDPR requires the doctor giving the instruction to put the oral instruction into writing within 24 hours. However, section 78D of the HDPR prohibits the administration of a medicinal cannabis product other than in accordance with a prescription written by a patient-class prescriber or a single-patient prescriber. The HDPR definition of *prescription* specifically excludes a written instruction.

Therefore, although nurses at a hospital may possess a controlled drug medicinal cannabis product, they cannot administer it.

Pharmacists are authorised under section 78I of the HDPR to obtain controlled drug medicinal cannabis and possess it at their dispensary for the purpose of issuing the product to persons authorised to obtain and possess it. Currently only patients for whom a patient-class prescriber or single-patient prescriber has written a prescription, those patients' carers, and patient-class prescribers and single-patient prescribers, are authorised to obtain and possess controlled drug medicinal cannabis.

Doctors are authorised under section 78F and 78G of the HDPR to perform regulated activities with controlled drug medicinal cannabis, but only if they are a patient-class prescriber or a single-patient prescriber, respectively. As such, unless a doctor at a hospital is specifically authorised or approved to use an S8 medicinal cannabis product, they cannot prescribe or make a written instruction for this product, nor perform any other regulated activity with the product.

The Act authorises an *eligible person* to deal with medicinal cannabis. This term is defined to include a health practitioner, which includes a doctor, nurse and pharmacist, or a class of persons prescribed by regulation. A regulation may also prescribe the way in which a class of eligible person may deal with medicinal cannabis. Therefore, the Act provides mechanisms

for doctors, nurses and pharmacists employed at a hospital to have the necessary specific authorities to continue the patient's medicinal cannabis treatment.

Unfortunately, no similar mechanisms exist in the HDPR. The Amendment Regulation closes this identified gap in the current medicinal cannabis regulatory framework.

Manufacturing of medicinal cannabis products

On 30 October 2016, the Commonwealth licensing and permit scheme for the cultivation, production and manufacture of medicinal cannabis commenced. Under this scheme, a manufacturer will be required to hold the following Commonwealth authorities, granted under the *Narcotic Drugs Act 1967* (Cwlth):

- licence to manufacture, and
- permit to manufacture.

The scheme also requires a manufacturer to hold the following state authorities:

- licence to manufacture, and
- licence to wholesale.

The granting of a Commonwealth manufacturing licence does not require state licences to manufacture and wholesale to be in place as a prerequisite. However, a Commonwealth manufacturing permit will not be issued if the licensee does not have these state licences.

In Queensland, sections 42 and 46 of the HDPR empower the chief executive to grant a controlled drug manufacturer licence and a controlled drug wholesaler licence, respectively. Section 43(b)(i) also provides that the holder of a controlled drug manufacturer licence is deemed to hold a controlled drug wholesaler licence.

As such, given the pending 1 November 2016 re-scheduling decision noted above, the HDPR already allows Queensland to issue the necessary manufacturing and wholesale licences for those medicinal cannabis products most likely to be used for individual patient treatment.

However, although the HDPR makes it an offence to manufacture a controlled drug unless the person has a controlled drug manufacturer licence, section 45(b) of the HDPR then provides that no offence is committed if this manufacture occurs pursuant to a licence, permit or other authority under the *Narcotic Drugs Act 1967* (Cwlth). As such, it is arguable that once a person obtains a Commonwealth manufacturing licence, the HDPR does not compel the person to also obtain a state licence to manufacture. Similarly, section 49(b) of the HDPR provides an exemption from holding a controlled drug wholesaler licence where a person manufactures pursuant to a licence, permit or other authority under the *Narcotic Drugs Act 1967* (Cwlth).

No Queensland manufacturer holds a licence, permit or other authority under the *Narcotic Drugs Act 1967* (Cwlth). The Amendment Regulation will ensure any manufacturer who applies for a Commonwealth authority must also apply for a state licence.

Access control to para-aminopropiophenone

The SUSMP may prescribe additional controls for certain substances, particularly where there are high dangers associated with their use. The SUSMP has implemented additional controls to restrict access to a newly scheduled regulated poison, para-aminopropiophenone (PAPP), a pest animal baiting poison. Under these controls, only an authorised or licensed person may carry out regulated activities with this regulated poison. All states and territories have agreed to apply these SUSMP controls under their respective relevant legislation. In Queensland, the relevant legislation is the HDPR.

PAPP has been approved by the Australian Pesticides and Veterinary Medicines Authority as a baiting product for vertebrate animals such as wild dogs and foxes. It is a highly dangerous pest animal baiting poison. Human ingestion of PAPP may result in death, particularly in young children.

In applying the SUSMP controls to PAPP, appendix 7 of the HDPR was previously amended to include PAPP as a regulated poison. However, PAPP was not specifically mentioned in section 271(2), alongside fluoroacetic acid and strychnine, as a regulated poison whose use attracts the additional controls under section 271(1), even where that use is in accordance with its registered purpose.

To adopt these additional controls for PAPP, an amendment to section 271(2) is required to specifically mention PAPP in the list of appendix 7 regulated poisons which are not excluded from the controls under section 271(1), even when being used in accordance with their registered purpose. Consistent with the SUSMP controls, this will have the effect of restricting the availability of PAPP to authorised persons only.

The amendment is required in the interest of public health and safety. A new product containing PAPP was released on the market in Queensland in June 2016. To prevent this product being used by unauthorised persons, an amendment to the HDPR is required to establish the framework for authorisation to occur. Through ongoing discussions with the manufacturer, the Department of Health understands that the poison has not been supplied to unauthorised persons to date.

Achievement of policy objectives

Queensland medicinal cannabis regulatory framework

To give effect to the practical implications of the TGA's pending re-scheduling decision, the Amendment Regulation modifies the purposes for which the chief executive may approve use of an S9 medicinal cannabis product. In lieu of approving individual patient treatment with an S9 medicinal cannabis product, the chief executive is now empowered to approve this product being used for research or analysis purposes. The existing power of the chief executive to approve use of an S9 medicinal cannabis product in an approved clinical trial is not affected.

Continuity of medicinal cannabis treatment during hospitalisation

To address the gaps in regulatory coverage for a medicinal cannabis product used at a hospital, and thereby ensure continuity of patient treatment with that product, the Amendment Regulation authorises the following persons to perform the following regulated activities:

- a doctor employed at a hospital is authorised to obtain, possess, supply and administer a medicinal cannabis product, and is also authorised to give an oral or written instruction for the administration of a medicinal cannabis product
- a registered nurse employed at a hospital is authorised to obtain, possess, supply and administer a medicinal cannabis product on the oral or written instruction of a doctor employed at the hospital
- an enrolled nurse employed at a hospital is authorised to obtain, possess, supply and administer a medicinal cannabis product on the written instruction of a doctor employed at the hospital
- a pharmacist employed at a hospital is authorised to obtain, possess, issue and supply a medicinal cannabis product on the oral or written instruction of a doctor employed at the hospital, and
- a hospital pharmaceutical assistant acting under the supervision of a pharmacist is authorised to possess and issue medicinal cannabis on the oral or written instruction of a doctor employed at the hospital.

This is achieved by amending the HDPR to ensure the extended authorities apply to patients prescribed S8 medicinal cannabis products.

When the patient is discharged from hospital, the doctor in the community who was specifically authorised or approved to use an S8 medicinal cannabis product will again become the only doctor allowed under the HDPR to prescribe that product to the patient. Any conditions applicable to this community doctor about mandated treatment dosages will not apply to the hospital doctor while the patient is in hospital, as the medicinal cannabis treatment must be able to be adjusted as needed to align with other treatment the patient is receiving in hospital.

The amendments permit the doctor at the hospital to alter dosages as needed and clarify that when treatment reverts back to the community doctor following release from hospital, the pre-hospital treatment conditions, including dosage, again apply.

Finally, to align the controlled drug manufacturing and wholesaling licensing requirements with the Commonwealth licensing and permit scheme for local manufacture of medicinal cannabis products, the Amendment Regulation removes an exemption to effectively require a person to hold a Queensland controlled drug manufacturer licence even if they hold a Commonwealth manufacturing licence for the product to be manufactured. A corresponding consequential change is also made in relation to controlled drug wholesaler licences.

Access control to para-aminopropiophenone

Finally, the Amendment Regulation specifically identifies PAPP as a regulated poison which remains subject to the controls under section 271(1), even when used in accordance with the

purpose for which it is registered by the Australian Pesticides and Veterinary Medicines Authority. This will meet the restricted access requirements for PAPP as specified by the SUSMP by ensuring it is only available to authorised persons.

There is also a minor related amendment to Appendix 7, item 7, to correct the spelling of the term 'para-aminopropiophenone'.

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 through the repeal of the S8 controlled drug medicinal cannabis provisions in the HDPR when the corresponding provisions of the Act commence.

Alternative ways of achieving policy objectives

The Amendment Regulation is the only means of achieving the policy objectives in the short term. The Act is intended to address those policy objectives relating to the regulatory framework for medicinal cannabis 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 the fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*.

Consultation

There has been no external consultation, as both the medicinal cannabis and PAPP amendments are considered necessary in the interests of public health and safety.

The amendments to ensure continuity of treatment with medicinal cannabis will provide clarity for patients and doctors when a patient being treated with medicinal cannabis is admitted to hospital. The amendments in relation to manufacturing of medicinal cannabis and updating the purposes for which S9 medicinal cannabis products may be approved are both required to support Commonwealth changes.

In relation to PAPP, the amendment is consistent with national control measures.

Notes on provisions

Short title

Clause 1 provides that, when made, the short title of the regulation will be the *Health (Drugs and Poisons) Amendment Regulation (No. 3) 2016*.

Regulation amended

Clause 2 provides that the regulation amends the *Health (Drugs and Poisons) Regulation 1996* (HDPR).

Amendment of s 45 (Offence to manufacture controlled drugs without licence)

Clause 3 amends section 45 to remove the exemption of not requiring a Queensland controlled drug manufacturing licence if the manufacturing activity is carried out under a *Narcotic Drugs Act 1967* (Cwlth) licence, permit or other authority.

Replacement of s 49 (Offence to wholesale controlled drugs without licence)

Clause 4 amends section 49 to remove the exemption of not requiring a Queensland controlled drug wholesaler licence if the related manufacturing activity is carried out under a *Narcotic Drugs Act 1967* (Cwlth) licence, permit or other authority.

Amendment of s 78B (Definition for part)

Clause 5 amends section 78B to insert definitions of *authorised person*, *chief executive approval*, *dosage condition* and *eligible hospital patient*, and makes a typographical change to the definition of *medicinal cannabis*.

Authorised person means a person at a hospital, authorised under this part to administer or supply medicinal cannabis to an eligible hospital patient at the hospital.

Chief executive approval means an approval to carry out regulated activities with medicinal cannabis granted by the chief executive under section 78K for an approved clinical trial.

Dosage condition means a condition relating to the dosage of medicinal cannabis that may be prescribed or used by a person. The condition may be imposed on a medicinal cannabis approval, the authority of a patient-class prescriber or single-patient prescriber, or a chief executive approval for a clinical trial.

Eligible hospital patient means a patient who has been admitted to a hospital and is being treated with medicinal cannabis by a patient-class prescriber or a single-patient prescriber, or in an approved clinical trial.

Amendment of s 78C (Purpose of part)

Clause 6 inserts new subparagraphs 78C(a)(iii) and (iv), to expand the purpose of the part to include the provision of regulated access to controlled drug medicinal cannabis through the treatment of eligible hospital patients and participants in approved clinical trials.

Amendment of s 78D (Application of part)

Clause 7 amends section 78D to adjust which HDPR provisions apply to the new framework for treatment with medicinal cannabis.

Section 78D was inserted in anticipation of medicinal cannabis products being rescheduled in the Commonwealth *Poisons Standard 2015*, also known as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), from a poison (S9) to a controlled drug (S8). This rescheduling allows the existing controlled drug provisions in the HDPR to also apply to medicinal cannabis. Section 78D excludes some of these provisions from applying, either because those provisions are not relevant to medicinal cannabis treatment or the particular controls around using medicinal cannabis demand alternate replacement provisions. The amendments in relation to hospital-based treatment with medicinal cannabis necessitate changes to these exclusions.

Clause 7 makes the following amendments to section 78D(2):

- It amends subsection (d) to omit reference to subsections 58A(3) and 58A(4). Section 58 authorises enrolled nurses to carry out regulated activities with controlled drugs. By excluding subsections 58A(3) and (4) from applying to the medicinal cannabis framework, section 78D(2)(d) prevented trainee enrolled nurses from carrying out those activities with a controlled drug medicinal cannabis. The effect of removing reference to those subsections in section 78D is that all of section 58 is now excluded, however enrolled nurses (but still not trainees) are authorised under the new section 78GB.
- It omits subsections (i) and (j), which exclude sections 66 and 69, respectively. By excluding sections 66 and 69, section 78D(2) prevented Queensland ambulance service officers and ships' masters, respectively, from carrying out regulated activities with controlled drug medicinal cannabis. However, these sections continue to be excluded under the amendment below which omits reference to all sections from 66 to 69.
- It inserts a new subsection 78D(2)(ea), which excludes section 59 from applying to medicinal cannabis. Section 59 authorises various hospital staff to carry out regulated activities with controlled drugs, but may now be excluded because amendments below provide hospital-specific authorities for doctors, nurses and pharmacists in relation to controlled drug medicinal cannabis. However, the exclusion of section 59 is qualified, meaning that section still applies to the extent needed to authorise other lead hospital staff (e.g. the medical superintendent of the hospital) to obtain, possess and issue controlled drug medicinal cannabis.
- The clause inserts a new subsection (i) excluding sections 66 to 69. As noted above, this amendment retains the existing exclusion of sections 66 and 69. However, the amendment now also excludes sections 67 and 68, which authorise registered nurses and certain registered nurses at a rural hospital, respectively, to carry out regulated activities with controlled drugs. Registered nurses (but not those in rural areas) are authorised instead under the new section 78GC.
- Clause 7 inserts a new subsection (n) excluding chapter 2, part 5 (sections 89 to 93). This part, which deals with obtaining and selling controlled drugs on purchase order, is not relevant to the medicinal cannabis framework as controlled drug medicinal cannabis will not be obtained or sold on a purchase order.

- It inserts a new subsection (o) excluding sections 119(4) and (5). Section 119 prescribes requirements for storage of controlled drugs, and sections 119(4) and (5) deal with an ambulance officer, doctor, nurse practitioner, rural and isolated practice area endorsed nurse or veterinary surgeon possessing a controlled drug at a place other where the person practises their profession. Possession of medicinal cannabis at such other places will not be permitted.
- It inserts a new subsection (p), which excludes sections 120 and 122. These sections, in relation to giving notice of lengthy treatment with a controlled drug and needing approval to treat certain drug dependent persons with controlled drugs, respectively, are unnecessary given the other controls around treatment with a medicinal cannabis product.

Subsections 78D(2)(ea) to (i) are renumbered as subsections (f) to (j).

Clause 7 also omits and replaces section 78D(3). The existing subsection 78D(3)(a) clarified that only a patient-class or single-patient prescriber could give a prescription for controlled drug medicinal cannabis, and the new subsection 78D(3)(a) mirrors this provision. The new subsection 78D(3)(b) provides that only hospital doctors can give an oral or written instruction for the supply or administration of controlled drug medicinal cannabis at a hospital. The existing subsection 78D(3)(b) clarified that a person cannot administer medicinal cannabis controlled drugs other than in accordance with the prescription of a patient-class or single-patient prescriber, and the new clause 78D(3)(c) mirrors and extends this provision to also cover supply and to recognise the supply and administration of controlled drug medicinal cannabis under the lawful instruction of a hospital doctor or in an approved clinical trials.

Finally, clause 7 inserts a new section 78D(4) to clarify that controlled drug medicinal cannabis is not required to be obtained on a purchase order.

Insertion of new ss 78GA to 78GC

Clause 8 inserts a new section 78GA, extending the authority to administer or supply controlled drug medicinal cannabis to doctors working in hospitals.

Inserted sections 78GB and 78GC extend the authority to carry out regulated activities with controlled drug medicinal cannabis to enrolled nurses and registered nurses, respectively, working in hospitals.

Clause 6 also extends the definition of *hospital*, for the purposes of new sections 78GA to 78GC, to include a hospice and a medical centre at a prison.

Amendment of section 78I (Pharmacists)

Clause 9 inserts new subsections 78I(1)(c), (2A) and (2B) to extend the authority of hospital pharmacists to carry out regulated activities with controlled drug medicinal cannabis. As with clause 6, new subsection 78I(3) is also inserted to provide an extended definition of *hospital* for the purpose of this section.

Clause 9 also renumbers section 78I consequent to the insertion of new subsections (2A) and 2(B).

Insertion of new s 78IA

Clause 10 inserts new section 78IA to authorise hospital pharmaceutical assistants, under the supervision of a pharmacist, to carry out regulated activities with controlled drug medicinal cannabis.

Amendment of s 78P (Expiry of part)

Clause 11 amends section 78P to prescribe a later automatic expiry date for chapter 2, part 3A of 30 June 2017, in the event the *Public Health (Medicinal Cannabis) Act 2016* has not commenced by 1 January 2017.

Amendment of s 270B (Approval for cannabis)

Clause 12 amends section 270B to modify the purposes for which the chief executive may approve use of an S9 medicinal cannabis product. In lieu of approving individual patient treatment with an S9 medicinal cannabis product, the chief executive is empowered to approve this product being used for research or analysis purposes. The existing power of the chief executive to approve use of an S9 medicinal cannabis product in an approved clinical trial is unaffected.

Amendment of s 271 (Prohibition on dispensing etc. regulated poisons)

Clause 13 amends section 271(2) to include the regulated poison para-aminopropiophenone with the existing references to fluoroacetic acid and strychnine. This has the effect of preventing use of this regulated poison by any unauthorised person.

Amendment of appendix 7 (Regulated poisons)

Clause 14 amends Appendix 7, item 7, to correct the spelling of the term ‘para-aminopropiophenone’.