Public Health (Medicinal Cannabis) and Other Legislation Amendment Regulation 2018

Explanatory Notes for SL 2018 No. 133

made under the

Health Act 1937
Public Health (Medicinal Cannabis) Act 2016

General Outline

Short title

Public Health (Medicinal Cannabis) and Other Legislation Amendment Regulation 2018

Authorising law

Section 180 of the *Health Act 1937*
Sections 52 and 217 of the *Public Health (Medicinal Cannabis) Act 2016*

Policy objectives and the reasons for them

The object of the *Public Health (Medicinal Cannabis) Act 2016* (Medicinal Cannabis Act) is to provide for regulated access to medicinal cannabis in Queensland through:

- the prescription of medicinal cannabis, under a system of medicinal cannabis approvals, by single-patient prescribers
- the prescription of medicinal cannabis, without medicinal cannabis approvals, by patient-class prescribers.

The *Public Health (Medicinal Cannabis) Regulation 2017* (Medicinal Cannabis Regulation) prescribes matters to support the regulatory framework established by the Medicinal Cannabis Act.

The policy objective of the *Public Health (Medicinal Cannabis) and Other Legislation Amendment Regulation 2018* (Amendment Regulation) is to streamline this regulatory framework, expand patient access to medicinal cannabis, including nabiximols, reduce regulatory reporting for pharmacists and medical practitioners, and remove unnecessary information requirements.

Expand patient-class prescriber pathway

Access to medicinal cannabis is regulated under both State and Commonwealth legislation. Except for one product, nabiximols, medicinal cannabis products are not registered in the Australian Register of Therapeutic Goods. Medical practitioners wishing to treat a patient with unregistered medicinal cannabis need to apply for access through a Commonwealth Therapeutic Goods Administration access scheme such as the Special Access Scheme. This scheme provides for the import and/or supply of an unapproved therapeutic good for a single patient on a case-by-case basis.

In Queensland, the Medicinal Cannabis Act provides two pathways for a patient to receive treatment with medicinal cannabis:

- Single-patient prescriber pathway – a medical practitioner who believes their patient may benefit from treatment with medicinal cannabis may apply to the chief executive of Queensland Health for an approval to prescribe the product for the patient.
- Patient-class prescriber pathway – the Medicinal Cannabis Regulation provides for a class of specialist doctors who have an as-of-right authority to prescribe specific medicinal cannabis products for patients with particular conditions, without the need for any additional chief executive approval.

The Medicinal Cannabis Regulation provides that specialists in the fields of oncology, palliative medicine, neurology, paediatrics and haematology are specialist medical practitioners who may prescribe medicinal cannabis as a patient-class prescriber.

The approval processes under the Commonwealth Special Access Scheme and Queensland's single-patient prescriber pathway are duplicative. The policy objective is to extend the less onerous patient-class prescriber pathway to all specialist medical practitioners, including specialist general practitioners.

The Medicinal Cannabis Regulation also provides for the class of patients to whom a patient-class prescriber may prescribe medicinal cannabis to include those experiencing chemotherapy induced nausea or vomiting, terminally ill persons undergoing palliative care, children with intractable epilepsy, or persons with multiple sclerosis experiencing spasticity.

The Amendment Regulation will extend the patient-class prescriber pathway to include persons suffering chronic non-cancer pain. However, it is a medical practitioner's role to advise patients on the appropriate use of medicines for the patient's particular circumstances or condition. Practitioners will be able to consider the national guidance documents published by the Therapeutic Goods Administration on its website about the use of medicinal cannabis in Australia as a resource to assist in making informed decisions.

Patient access to the approved drug nabiximols

The medicinal cannabis drug nabiximols, also known by the brand name Sativex, is registered on the Australian Register of Therapeutic Goods and is approved for use in treating patients experiencing spasticity arising from multiple sclerosis. As it is a registered medicine, it is regulated under the *Health (Drugs and Poisons) Regulation 1996* rather than under the Medicinal Cannabis Act.

A policy objective of the amendments is to expand patient access to nabiximols under the Health (Drugs and Poisons) Regulation consistent with the amendments proposed to the Medicinal Cannabis Regulation.

Achievement of policy objectives

To achieve the policy objective of streamlining the regulatory framework and expanding patient access to medicinal cannabis, the Amendment Regulation will amend the Medicinal Cannabis Regulation to:

- expand the prescribed class of specialist medical practitioners for the patient-class prescriber pathway to all specialist medical practitioners
- expand the prescribed classes of patients to whom a patient-class prescriber may prescribe medicinal cannabis to include persons suffering chronic non-cancer pain
- reduce reporting requirements for patient-class prescribers by requiring them to provide patient treatment reports to the chief executive on request rather than at the frequency stated in the guideline published by the Chief Health Officer
- reduce reporting requirements for medicinal cannabis dispensers, that is pharmacies, by requiring them to report when dispensing medicinal cannabis weekly, rather than within 72 hours (this aligns with the reporting of other Schedule 8 drugs)
- remove the requirement for a wholesaler's professional qualifications to be included on a wholesaling approval.

Consistent with the amendments proposed to the Medicinal Cannabis Regulation, patient access to nabiximols under the Health (Drugs and Poisons) Regulation will be expanded by giving all specialist medical practitioners the authority to treat patients with specified conditions. The amendments include chronic non-cancer pain as one of these prescribed conditions.

Consistency with policy objectives of authorising law

The Amendment Regulation is consistent with the policy objectives of the Medicinal Cannabis Act.

Inconsistency with policy objectives of other legislation

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

Alternative ways of achieving policy objectives

The Amendment Regulation is the only effective means of expanding patient access to medicinal cannabis within the existing legislative framework.

Benefits and costs of implementation

The Amendment Regulation will improve patient access to medicine and streamline the regulatory burden on medical practitioners and pharmacies involved in the prescribing and dispensing of medicinal cannabis. There are no significant cost implications.

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 following stakeholders were consulted on the amendments:

- Queensland Medicinal Cannabis Expert Advisory Panel
- Pharmaceutical Society of Australia
- Pharmacy Guild (Queensland)
- Hospital and Health Services, Queensland Health
- Royal Australian College of General Practitioners
- Australian Medical Association Queensland
- Royal Australasian College of Surgeons
- Royal Australian College of Physicians
- Secretariat – Medical Specialist Colleges
- Queensland Regional Committee, Faculty of Pain Medicine of the Australian and New Zealand College of Anaesthetists
- Australian College of Rural and Remote Medicine
- Health Consumers Queensland.

No significant issues were raised by stakeholders. Overall the amendments to increase patient access and extend the class of patient-class prescribers are supported.

The Queensland Productivity Commission was consulted and considers the proposed amendments do not require further regulatory impact assessment under the *Queensland Government Guide to Better Regulation*.

Notes on provisions

Part 1 Preliminary

Short title

Clause 1 provides the short title of the regulation.

Part 2 Amendment of Health (Drugs and Poisons) Regulation 1996

Regulation amended

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

Amendment of s 78A (Approved drug–nabiximols)

Clause 3 amends section 78A to extend the classes of specialist medical practitioners authorised to dispense, prescribe, supply or use nabiximols to all specialist medical practitioners. The clause also extends the class of patients which may be treated with nabiximols to include persons suffering chronic non-cancer pain.

Amendment of s 78B (Exemptions for some acts involving regulated controlled drugs)

Clause 4 makes an amendment to section 78B to remove unnecessary subsections (2) to (4) as the following provisions may be relied on:

- section 58(1)(d) – doctors are authorised to give oral and written instructions about controlled drugs to persons authorised to administer or supply the drug
- section 67(4) – nurse practitioners are authorised to give oral and written instructions about controlled drugs to various persons
- section 67(1) – registered nurses are authorised to administer a controlled drug on the oral or written instruction of a doctor or nurse practitioner
- section 78A(1) – does not prevent doctors and nurse practitioners from giving oral or written instructions for regulated controlled drugs.

Part 3 Amendment of Public Health (Medicinal Cannabis) Regulation 2017

Regulation amended

Clause 5 provides that part 3 amends the *Public Health (Medicinal Cannabis) Regulation 2017*.

Amendment of s 27 (Form of wholesaling approval)

Clause 6 amends section 27(a) by removing the requirement that an instrument for a wholesaling approval must contain the wholesaler's professional qualifications.

Amendment of s 54 (Prescribed specialist medical practitioners—Act, s 52(1)(a))

Clause 7 amends section 54(1) to prescribe that all compliant specialist medical practitioners are patient-class prescribers for section 52(1)(a) of the Act. A 'compliant' specialist medical practitioner is defined in section 54(2).

Amendment of s 55 (Prescribed classes of patients—Act, s 52(2)(a))

Clause 8 amends section 55 to add persons experiencing chronic non-cancer pain to the classes of patients to whom a patient-class prescriber may prescribe medicinal cannabis.

Clause 8 also inserts a definition for chronic non-cancer pain.

Amendment of s 89 (Dealing with prescriptions)

Clause 9 amends section 89(4) to require a dispenser to provide information about medicinal cannabis dispensed on prescription to the chief executive within seven days after dispensing it.

Amendment of s 127 (Patient-class prescribers)

Clause 10 amends section 127(2) to provide that, if requested by the chief executive, a patient-class prescriber must provide a treatment report on an eligible patient to the chief executive within the period specified in the request.