Health (Drugs and Poisons) (Cannabis and Other Matters) Amendment Regulation 2018

Explanatory notes for SL 2018 No. 21

made under the

Health Act 1937

General Outline

Short title

Health (Drugs and Poisons) (Cannabis and Other Matters) Amendment Regulation 2018

Authorising law

Section 180 of the *Health Act 1937*

Policy objectives and the reasons for them

The *Health (Drugs and Poisons) (Cannabis and Other Matters) Amendment Regulation 2018* amends the *Health (Drugs and Poisons) Regulation 1996* (HDPR). The HDPR provides authority for health practitioners in Queensland to use medicines and poisons. The amendments to the HDPR facilitate and streamline patient treatment, ensure consistency with state and Commonwealth legislation and update references to national guidelines and codes.

Medicinal cannabis

Nabiximols, also known by the brand name Sativex, is a medicinal cannabis product. Nabiximols is registered on the Australian Register of Therapeutic Goods (ARTG) and is approved for use in treating patients experiencing spasticity arising from multiple sclerosis.

The *Public Health (Medicinal Cannabis) Act 2016* (Medicinal Cannabis Act) commenced on 1 March 2017. It facilitates patient access to medicinal cannabis products that are not registered on the ARTG. Therefore, nabiximols remains regulated under the HDPR.

Section 78A of the HDPR only allows a specialist medical practitioner in neurology or rehabilitation medicine, or their registrar, to prescribe nabiximols. As this is an ARTG-registered medical cannabis product, these specialists may only use it to treat conditions for which it is approved, being patients experiencing spasticity arising from multiple sclerosis.

Under the Medicinal Cannabis Act, doctors may prescribe unregistered medicinal cannabis products in two ways. Firstly, a patient-class prescriber has an as-of-right authority to use a particular product to treat a particular medical condition. The *Public Health (Medicinal Cannabis) Regulation 2017* lists the classes of specialists who are patient-class prescribers and the conditions they may treat. Secondly, a single-patient prescriber may use any product to treat any condition, provided this is first approved by the chief executive of Queensland Health.

The policy intention of the amendments is to expand patient access to nabiximols, in a similar manner as if it were regulated under the Medicinal Cannabis Act.

Access to first aid medicine in school and childcare settings

Schools have a general duty of care to take reasonable steps to ensure the safety of their students. Under guidelines issued by the Department of Education and Training, this duty includes maintaining suitably equipped first aid kits. Similarly, education and child care services, such as day-care and preschool services, are required to have suitably equipped first aid kits under the *Education and Care Services National Law (Queensland).*

The medicines considered a necessary component of a suitably equipped first aid kit are asthma inhalers, which contain the schedule 3 (S3) substances salbutamol and terbutaline, and adrenaline auto-injectors (also known by the brand name EpiPens) used in the treatment of anaphylaxis, which contain the S3 substance adrenalin. S3 substances are classed as a poison under the HDPR, but are more accurately known as a pharmacy medicine under the national *Standard for the Uniform Scheduling of Medicines and Poisons*.

Section 277 of the HDPR prohibits the sale of an S3 product by a pharmacist unless the seller is reasonably satisfied of the purchaser's identity and therapeutic need for the product. The product must have a label with the name of the person for whom the product is intended to treat. These restrictions mean a pharmacist cannot sell asthma inhalers or adrenaline auto-injectors to a school or education and care service where the products are intended for a first aid kit to treat any child needing future emergency treatment.

Some schools and education and care service have obtained the necessary first aid stock from drug wholesalers or under specific approvals granted by the chief executive. However, this process is cumbersome and costly. In other cases, the school or education and care service relies on the rescue medication brought in by individual children. However, this may leave other children without access to treatment in an emergency.

The policy intention of the amendments is to streamline the process for the persons in charge of schools and education and care services, or another nominated person, to obtain the necessary rescue medication.

Isolated practice areas

Indigenous health workers and isolated practice area paramedics, endorsed nurses and midwives are authorised under the HDPR to exercise specific expanded functions when working in an isolated practice area.

These functions enable indigenous health workers to obtain, possess or administer a schedule 4 (S4) restricted drug and schedule 8 (S8) controlled drug, and administer or supply a schedule 2 (S2) or S3 poison. Isolated practice area paramedics can obtain, supply or administer an S8 controlled drug and obtain, possess administer or supply an S4 restricted drug, or S2 or S3 poison. Isolated practice area endorsed nurses can obtain, possess or administer an S8 controlled drug, obtain, possess, supply or administer an S4 restricted drug, and similar to isolated practice area midwives, supply an S2 or S3 poison.

The effect of these expanded functions is to enable health practitioners to respond appropriately, ensuring the health and safety of the community in remote and isolated parts of Queensland. Through a technical error following local government zoning changes, a number of localities have unintentionally been removed from the isolated practice area designation. Health practitioners are unable to utilise their expanded functions in Mapoon, Douglas, Mareeba and Torres Strait Island.

A correction is required to restore the ability of isolated practice area health workers to utilise their expanded functions in these isolated practice areas.

Pandemic drug therapy protocol

A drug therapy protocol is a certified document published by the Department of Health stating the circumstances in which a person may use a specified S4 restricted drug or S8 controlled drug. These circumstances often arise in times of emergency when the use of antivirals or vaccines is needed, such as in the event of an influenza pandemic.

The HDPR requires an *influenza epidemic proclamation* to have been declared by the Commonwealth Government under the *Quarantine Act 1908* before the Department of Health can invoke the Pandemic Influenza Drug Therapy Protocol. However, the Commonwealth repealed the *Quarantine Act 1908* in 2016 and replaced it with the *Biosecurity Act 2015*. The *Biosecurity Act 2015* also replaced the term *influenza epidemic proclamation* with *influenza emergency declaration*.

Amendments are required to update references to Commonwealth legislation and terminology, to enable the Pandemic Influenza Drug Therapy Protocol to be invoked when needed.

Electronic purchase forms

The HDPR allows for the wholesale purchase, invoice and receipt of scheduled medicines. Signatures relevant to the purchase, invoice and receipt of scheduled medicines must comply with the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use*.

This code has been superseded and electronic purchase forms are now available for use under the *Australian Code of Good Wholesaling Practice for Medicines in schedules 2, 3, 4 & 8*.

Amendments will adopt the new code, enabling streamlined health purchasing practices.

Update references to podiatry guidelines

The Podiatry Board of Australia regulates podiatrists in Queensland and updates protocols and procedures in their guidelines accordingly. The current edition, *Guidelines for Endorsement of Scheduled Medicines* (the podiatry guideline), is under review and expected to be replaced with an updated version.

The podiatry guideline is currently referenced by title in the HDPR for the purpose of defining an *endorsed podiatrist*.

Amendments are required to enable the Podiatry Board of Australia to update their guidelines without needing to amend the HDPR each time the title of the document changes.

Achievement of policy objectives

Medicinal cannabis

The amendments broaden patient access to nabiximols to be consistent with access to medicinal cannabis products under the Medicinal Cannabis Act.

The amendments expand the authority to dispense, prescribe, supply or use nabiximols to include those specialist medical practitioners authorised as patient class prescribers under the Medicinal Cannabis Act. These specialists will only be authorised to treat the listed range of conditions they are authorised to treat under the Medicinal Cannabis Act.

The amendments also expand the authority to dispense, prescribe, supply or use nabiximols to include any doctor approved by the chief executive of Queensland Health to do those activities. This new authority equates to the case-by-case authority of a single-patient prescriber under the Medicinal Cannabis Act. Approvals by the chief executive are granted under section 18 of the HDPR.

The amendments apply the key conditions relevant to a patient-class and single-patient prescriber under the Medicinal Cannabis Act to all doctors now authorised under the HDPR to prescribe nabiximols. As a doctor is not authorised to sell a drug, the amendments replace references in section 78A to ‘sell’ with ‘supply’. The amendments also 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.

Finally, as clinical trials using unregistered medicinal cannabis products are now regulated under the Medicinal Cannabis Act, an obsolete reference to these trials in the dictionary has been removed. Any clinical trial using nabiximols would continue to be regulated under the HDPR.

Access to first aid medicine in school and childcare settings

To enable schools and education and care services to discharge their duty of care, the amendments streamline the process of purchasing emergency rescue medication, particularly asthma inhalers and adrenaline auto-injectors.

The amendments exempt relevant persons from complying with the conditions to purchase an S3 medication from a pharmacist. The relevant persons exempted are the principal of a school, or a person nominated by the principal, and the approved provider of an education and care service and a supervisor at the service. The amendments also allow a person approved by the chief executive of Queensland Health to administer an S3 poison under section 18 to be subject to the exemption.

Isolated practice areas

To achieve the policy intention of enabling isolated practice area health practitioners to utilise their expanded functions in all areas intended to be isolated practice areas, Mapoon, Douglas, Mareeba and Torres and Cape will be re-inserted into the list of prescribed isolated practice areas.

Pandemic drug therapy protocol

The amendments align the HDPR with Commonwealth legislation by replacing references to the *Quarantine Act 1908* with the *Biosecurity Act 2015* and the term *influenza epidemic proclamation* with *influenza emergency declaration*.

Electronic purchase forms

To allow for the electronic purchase, invoice and receipt of scheduled medicines, the amendments replace references to the repealed *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* with the current *Australian Code of Good Wholesaling Practice for Medicines in schedules 2, 3, 4 & 8*.

Update references to podiatry guidelines

The amendment simplifies how the *Guidelines for Endorsement for Scheduled Medicines* are referenced in the dictionary, to remove the need to amend the HDPR to make minor changes to the title of the guidelines in future.

Consistency with policy objectives of authorising law

The amendments are 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.

Alternative ways of achieving policy objectives

As the authorities for health practitioners and education and care services to use scheduled substances are provided by regulation, an amendment is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The amendments are not expected to impose costs on the persons or organisations to which they apply. The amendments relating to nabiximols will improve patient access to medicine. Similarly, the amendments relating to access to first aid medicine will streamline the process for schools and education and care services to access this medication. The other amendments make minor corrections and consequential changes to ensure existing provisions operate as intended and therefore do not impose any costs.

Consistency with fundamental legislative principles

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

Consultation

Representatives of Independent Schools Queensland and the Queensland Catholic Education Commission were consulted in relation to the amendments to streamline access to emergency medication for schools and education and care services. They support the amendments.

The amendments relating to nabiximols and access to first aid medication have been assessed by the Department of Health, in accordance with *The Queensland Government Guide to Better Regulation*, as being machinery in nature as they make no substantive change to policy. The remaining amendments have been assessed by the Department of Health as being consequential. Therefore, consultation with the Queensland Productivity Commission was not required.

Notes on provisions

Short title

Clause 1 provides the short title of the regulation.

Regulation amended

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

Amendment of s 48 (General conditions that apply to controlled drug wholesaler licence)

Clause 3 amends section 48 to align the reference to the code of good wholesaling practice for medicines with how that code is now defined in the dictionary.

Amendment of s 78 (Specified condition drugs—amphetamine, dexamphetamine, lisdexamfetamine, methylamphetamine, methyphenidate)

Clause 4 makes consequential changes to section 78 as a result of inserting new section 78B. The omitted subsections are now replicated within section 78B.

Replacement of s 78A (Approved drug—nabiximols)

Clause 5 replaces section 78A to extend the classes of medical practitioners authorised to dispense, prescribe, supply or use nabiximols. The clause also inserts new section 78B 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.

Amendment of s 142 (General conditions that apply to restricted drug wholesaler licence)

Clause 6 amends section 142 to align the reference to the code of good wholesaling practice for medicines with how that code is now defined in the dictionary.

Amendment of s 277 (Sale of S3 poisons)

Clause 7 amends section 277 to extend the classes of persons exempted under section 277(7) from the conditions applicable to dispensing schedule 3 poisons.

Amendment of appendix 5 (Areas of local governments forming isolated practice areas)

Clause 8 amends appendix 5 to include ‘Douglas’, ‘Mareeba’ and ‘Torres Strait Island’ within the definition of local governments forming isolated practice areas.

Amendment of appendix 9 (Dictionary)

Clause 9 amends appendix 9 to include new defined terms, amend existing definitions and remove defined terms no longer used in the HDPR.

Amendment of various sections

Clause 10 updates the terminology used in various sections to reflect changes in the dictionary and changes to Commonwealth legislation.