Medicines and Poisons Act 2019

Factsheet - current as at July 2024

Key legislative requirements – Medical practitioners

Introduction

The *Medicines and Poisons Act 2019* (MPA) and Medicines and Poisons (Medicines) Regulation 2021 (MPMR) and associated legislative instruments define the lawful actions in relation to medicines (schedule 2 (S2), 3 (S3), 4 (S4) and 8 (S8)) of the Poisons Standard[1]) for therapeutic use in Queensland.

The legislation and associated legislative instruments (including departmental standards and extended practice authorities) can be accessed from the Queensland Health site - Legislation, departmental standards and extended practice authorities.

The Poisons Standard, which contains the schedules for medicines and poisons and packaging and labelling requirements can be found at www.tga.gov.au/poisons_standard.

Appendix 1 in this fact sheet contains definitions for some of the commonly used terms. Refer to the full list of terms and associated definitions listed in the Dictionary in Schedule 1 of the MPA, and Schedule 22 of the MPMR for the full range of definitions.

Authority to deal with medicines

The MPMR has thirteen Schedules that contain the authorisations for people to carry out certain activities (or 'dealings') with medicines. People who have an authorisation to deal with a medicine in a Schedule are termed *approved persons*.

Schedule 6 of the MPMR sets out the types of activities (dealings), the medicines and the scope for dealing with the medicines (as-of-right authorisation) that may be carried out by approved persons who are:

Medical practitioners - generally (Part 1)

Specialist medical practitioners, including Registrars (Part 2)

Physician assistants (Part 3).

The MPA also enables the making of **Emergency Orders** in particular circumstances such as a declared public health emergency or a disaster situation. Emergency orders are an alternative authorisation for *approved persons* specified in the Emergency Order; the order may temporarily

[1] The legal title of the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) that details the schedules for medicines and poisons and packaging and labelling requirements - The Poisons Standard (the SUSMP) | Therapeutic Goods Administration (TGA).

extend or restrict an *approved person's* primary authorisation. Active Emergency Orders are published on the Updates and alerts web page.

Prescribing medicines

Medical practitioners may prescribe medicines for the treatment of patients under their care where the medical practitioner has assessed the medicines to be reasonably necessary for the therapeutic treatment of the patient.

A prescription is a direction that may be given orally or in writing, and may authorise:

- The dispensing of a medicine by a pharmacist or the giving of a treatment dose, for example, by nurses in rural hospitals (a prescription for supply); or
- The administration of a medicine (e.g. an entry on a medication chart).

From the date written, prescriptions for S2, S3 and S4 medicines are valid for *12 months*, while S8 medicine prescriptions are valid for *six months*. This applies to both prescriptions for supply and prescriptions for administration.

A quick reference guide on the requirements for writing prescriptions can be found in Writing lawful prescriptions.

Some requirements applying to medical practitioners issuing written prescriptions are highlighted below. Practitioners should also read Chapter 4 and Schedule 6 of the MPMR.

- It is a requirement that all prescriptions for monitored medicines include the date of birth of the patient.
- A prescription for supply for an S8 medicine must include the quantity to be supplied in words and numbers, however a paper prescription for an S8 medicine that has been generated on a computer does not require the particulars to be handwritten on the prescription other than a hand-written signature.
- A paper prescription for supply that has been generated on a computer may not be amended once it has been printed. If an error is identified after a prescription has been printed, the error must be corrected in the prescribing software and a new prescription generated.
- Prescribers must not self-prescribe or self-administer a high-risk medicine. High risk medicines include all S8 medicines, benzodiazepines, S4 codeine-containing medicines, gabapentin, pregabalin, quetiapine, tramadol, zolpidem and zopiclone. These medicines are also monitored medicines whose dispensing is recorded in the monitored medicines database, QScript.

Monitored medicines

Monitored medicines are medicines identified by Queensland Health as potentially presenting a high risk of harm to patients and the community as a result of overdose, dependence, misuse and/or diversion.

Before prescribing, dispensing or giving a treatment dose of a monitored medicine for a patient, a medical practitioner is required to check Qscript (unless an exemption under Schedule 18, Part 1A of the MPMR applies).

QScript provides real-time information about a patient's pattern of use of monitored medicines history to assist prescribers in identifying when a patient may be at risk of serious monitored medicines-related harms. See further details about QScript here: www.health.qld.gov.au/qscript.

Additionally, when prescribing a monitored medicine to be dispensed or given as a treatment dose, or when dispensing a monitored medicine for a patient, it is a requirement for the medical practitioner to comply with the provisions of the Departmental Standard: Monitored Medicines. This is a separate requirement to accessing QScript, however, the information in QScript may prompt the prescriber to implement appropriate strategies to reduce the risk of harm for a patient they are treating. The standard sets out mandatory minimum requirements.

If a medical practitioner is dispensing a monitored medicine on a prescription, they must comply with the Departmental Standard: Monitored Medicines for dispensing.

The fact sheet Compliance, monitoring and enforcement describes the approach to compliance, monitoring and enforcement for the requirement to access QScript under section 41 of the MPA as well as other provisions in the medicines and poisons regulatory scheme.

Restricted medicines

The authorities to deal with restricted medicines[2] are limited to certain types of prescribers. Medical practitioners should refer to Schedule 6 of the MPMR to determine if the prescription falls within the limits of the medical practitioner's *approved persons* authority in the schedule.

Prescribers who are not automatically authorised as an *approved person* to prescribe a restricted medicine under the MPMR may apply for a prescribing approval from Queensland Health.

Restricted medicines include *approved opioids* under the Queensland Opioid Treatment Program. All prescribers of *approved opioids* require a prescribing approval.

Note 1: A Queensland Health issued prescribing approval is separate to the approval to prescribe an authority PBS prescription item given by a delegate of the Commonwealth Department of Health.

Note 2: For patients who are being treated with a restricted medicine at the time they are admitted to a hospital, prison, watch-house or detention centre, a medical practitioner may prescribe the restricted medicine for the continuing treatment of the patient during their admission.

Prescribing approvals

A prescriber whose authorisation to prescribe a restricted medicine is because they hold a prescribing approval issued by Queensland Health must include the **prescribing approval number** on all prescriptions for the restricted medicine. The inclusion of the prescribing approval number is important because it enables the person acting on the prescription, such as the dispensing pharmacist, to be sure that the prescription is from a legitimate prescriber.

Note 3: A prescribing approval number is given by Queensland Health and is distinct from the approval numbers issued by the Commonwealth Department of Health, such as a PBS prescriber number or an MBS provider number.

Information about prescribing approvals including application forms and guidelines are available for *approved opioids*, psychostimulants and other restricted medicines at https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines/prescribing-approvals.

Standing orders

Medical practitioners may make a standing order for the treatment of patients at an aged care facility, hospital, prison or detention centre, or at a place used to provide an Aboriginal or Torres Strait Islander health service. Standing orders may not be made for use at any other place,

[2] Restricted medicines are listed in Part 1 of Schedule 2 of the MPMR

including medical practices and clinics, unless Queensland Health has approved the use of standing orders at that place.

A standing order must be approved by a medicines committee for the place where it is to be implemented. The informational elements that must be included in a standing order are now specified in the Regulation. See Part 7 of Chapter 4 of the Regulation for further information.

Clinical protocols

Clinical protocols are a special type of standing order, made by a medical practitioner, that applies in relation to a procedure or diagnostic test performed by a clinical perfusionist, respiratory scientists, nuclear medicine technologist, speech pathologist or orthoptist.

Further information about clinical protocols is available at: https://www.health.qld.gov.au/__data/assets/pdf_file/0017/1110761/fs-clinicians-working-under-clinical-protocol.pdf.

Supplying medicines to patients

A medical practitioner who supplies a S4 or S8 medicine to a patient must **attach a label to the medicine** and **make a record of the supply**. The requirements for labelling medicines that are supplied to patients (given as a treatment dose) are contained in section 134 of the MPMR while section 136 contains the information that must be in a record about the supply.

Substance management plans

A substance management plan sets out how known and foreseeable risks associated with medicines, as regulated substances, are to be managed at the regulated place. A responsible person at a regulated place must make a substance management plan that complies with the Department Standard – Substance Management Plans for medicines and is accountable for ensuring all employed or contracted staff are aware of and have access to the plan as a resource.

All medical practitioners who are employed or contracted at a place at which a substance management plan applies (a *regulated place*) must comply with the requirements for dealing with medicines specified in the substance management plan for that place. Places required to have a substance management plan are listed in Schedule 17 of the MPMR and include public and private hospitals, aged care facilities and pharmacies.

For more information on the content of a Substance Management Plan see the guidance document.

Other requirements

Storage and record-keeping

Medicines must be stored to maintain their integrity and limit the opportunity for diversion or unintended poisoning. The requirements for storing medicines are in Part 2 of Chapter 8 of the Regulation and in the Departmental Standard: Secure Storage of S8 Medicines.

Disposal of medicine waste (including S8 medicines)

Part 11 of Chapter 4 of the MPMR contains the requirements for disposing of medicines, including S8 medicines and other diversion-risk medicines. To prevent environmental contamination, medicines must not be disposed of as general waste. They may not be poured down a sink,

flushed down a toilet, or sent to landfill. Medicine waste must be destroyed by high temperature incineration by an approved waste management contractor.

Rather than sending S8 medicine waste to Forensic and Scientific Services for destruction (as was previously required under the HDPR), S8 medicine waste that has been **rendered unusable and unidentifiable** may now be included with other scheduled medicine waste that is sent away for incineration.

S8 medicine waste may also be transferred to another health practitioner (such as a pharmacist) for destruction if the person transferring the waste is satisfied that the person to whom they are transferring the waste is authorised to destroy the S8 medicine waste. A person receiving S8 medicine waste must acknowledge receipt of the waste by either:

a) signing an entry for the transfer in the medicine register for the S8 safe in which the waste was kept; or

b) signing a separate notice acknowledging the receipt.

Ambulance officers, dentists, medical practitioners, pharmacists, nurses, midwives, podiatrists, and veterinary surgeons are authorised to destroy S8 medicine waste if the destruction is witnessed by another person who is also authorised to destroy S8 medicines and who is not related, or in a de facto relationship with the person destroying the waste.

The requirement to have the destruction of S8 medicine waste witnessed does not apply to waste that is:

a) residue from a medicine in the form of—

(i) an unused portion of a tablet;

(ii) the unused partial contents of a previously sterile ampoule or container;

(iii) a used transdermal patch; and

b) destroyed immediately after the medicine is no longer required for administration.

The specific requirements for destroying S8 medicines are detailed in the information sheet – Disposal and destruction of diversion-risk medicine waste.

Reporting matters to the chief executive

There are reporting obligations for health practitioners under the MPA. The notification requirements are contained in Chapter 8 of the MPMR and include the requirement to notify lost or stolen S8 medicines, and for a pharmacist to notify non-receipt of a paper copy of a prescription that was sent to a pharmacy by digital communication (fax/email).

There are specific forms that must be used when notifying Queensland Health. These can be found on the Qld Health website at: https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/reporting-medicines-matters.

Associated guidance documents

- Factsheet – writing lawful prescriptions
- Factsheet – interstate prescribers
- QScript information
- Queensland Health Departmental Standard – Monitored medicines

For further information

Contact Medicines Approvals and Regulation Unit

MARU@health.qld.gov.au

Appendix 1 – Commonly used terms

Term	Meaning
Deals	A person deals or is dealing with a medicines as a regulated substance, if the person carries out any of the following - manufacture; buy; possess; supply (includes sell, dispense or give a treatment dose); administer, prescribe or make a standing order for medicines; apply a poison; and dispose of waste or otherwise use a prohibited substance.
Dispense	Dispense means to sell the medicine to a person on prescription i.e. on the authority of a prescriber.
Give a treatment dose	Distinct from 'dispense', to give a treatment dose of a medicine means to supply one or more doses of the medicine to a person to be taken by a particular person, or administered to an animal, at a later time.
High-risk medicine	The term used to collectively describe the group of medicines which may not be self-prescribed or self- administered (other than pursuant to lawful prescribing or supply). High-risk medicines are all S8 medicines, all benzodiazepines, codeine, gabapentin, pregabalin, quetiapine, tramadol, zolpidem and zopiclone
Monitored medicines	The term used to collectively describe the group of medicines (listed in Part 4 of Schedule 2 of the MPMR) whose use is monitored via real-time prescription monitoring (QScript).
Prescribe	A term that relates to the action of a practitioner authorising treatment with a medicine, either administration or supply, to be carried out by another person.
Regulated place	A place, listed in Schedule 17 of the MPMR, where a substance management plan applies.
Restricted medicine	The term used to collectively describe medicines that have additional restrictions on who can prescribe them. A medicine may be restricted because, for example, it is teratogenic or is in short supply. Restricted medicines are listed in Part 1 of Schedule 2 of the MPMR.
Supply	Supply is an umbrella term that includes to 'sell', 'dispense' and 'give a treatment dose' as particular types of supply but does not include to administer or to dispose of waste.