Queensland Health

Key legislative requirements – pharmacists

Medicines and Poisons Act 2019

Introduction

The *Medicines and Poisons Act 2019* (MPA) and the Medicines and Poisons (Medicines) Regulation 2021 (MPMR) 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, standards and extended practice authorities.

Commonly used terms and phrases

The MPA introduces new terminology and modifies terms previously used in the repealed *Health Act 1937* and repealed Health (Drugs and Poisons) Regulation 1996 (HDPR). **Appendix 1** in this fact sheet contains definitions for some of the commonly used terms. Other definitions can be found in the dictionaries of both the MPA and the MPMR.

Authorisation 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 9 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:

- Pharmacists - generally (Part 1, Division 1)
- Pharmacists employed at *particular places*[2] (Part 1, Division 1A)
- Pharmacists giving purchase orders at *relevant institutions*[3] (Part 1, Division 2)
- *Participating pharmacists* practising at *participating pharmacies*[4] (Part 1, Division 2A)
- Intern pharmacists (Part 1, Division 3)

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

[2] means a pharmacist employed at a community pharmacy or private health facility; or is a health service employee.

[3] means an aged care facility, hospital, prison or detention centre (refer to Schedule 22 of MPMR).

[4] under the community pharmacy scope of practice pilot.

- Trainee pharmacists[5] (Part 1, Division 4)
- Hospital pharmaceutical technicians (Part 2, Division 1)
- Dispensary pharmacy assistants (Part 2, Division 2)
- General pharmacy assistants (Part 2, Division 3)

Extended practice authorities

An 'Extended Practice Authority' (EPA) states the places or contexts an approved person may undertake additional regulated activities with medicines. EPAs impose conditions on dealings with the medicines specified and may require a person to hold particular qualifications or training.

EPAs allow authorisation to be provided to deal with particular medicines for particular circumstances within conditions, such as administering specified prescription-only (S4) medicines to a patient without a prescription when the general requirement is that administration of an S4 medicine is only on a prescription. The name 'extended practice' refers to the authority; it does not define the professional practice of the approved person authorised under the EPA as 'extended practice'.

Schedule 9, Part 1 of the MPMR establishes the Extended Practice Authority – pharmacists (EPA-Pharmacists). The authorisations and conditions are outlined in the EPA, including:

- the training requirements which are listed in Appendix 1; and
- the facility requirements which are listed in Appendix 3; and
- the authorised medicines that may be dealt with, which are listed in the remaining appendices, if the pharmacist meets the training and facility requirements.

Schedule 9, Part 2A of the MPMR establishes the Extended practice authority - Pharmacists - Community pharmacy scope of practice pilot, which authorises participating pharmacists who are practising in a participating pharmacy under the Queensland Community Pharmacy Scope of Practice Pilot to have specific dealings with medicines. For further detail, refer to the Queensland Community Pharmacy Scope of Practice Pilot website.

Departmental Standards

The MPA allows the chief executive to make a *departmental standard* about carrying out a regulated activity with a regulated substance. The departmental standards provide task-specific guidance for professions and industries that perform the relevant regulated activities with regulated substances. The MPMR provides guidance as to what persons or entities the relevant departmental standard applies to.

[5] means a person registered with the Australian Health Practitioner Regulation Agency (AHPRA) as a student or for training purposes.

The MPMR prescribes the following six departmental standards:

- Departmental Standard – Compounding;
- Departmental Standard – Monitored medicines;
- Departmental Standard – Pseudoephedrine recording;
- Departmental Standard – Secure storage of S8 medicines;
- Departmental Standard – Substance management plans for medicines;
- Departmental Standard – Requirements for an Electronic Prescription Management System (EPMS).

Pharmacists should be familiar with all the departmental standards, as they are all applicable to pharmacists working in a variety of pharmacy settings.

Substance Management Plans (SMPs)

A requirement of the MPA is that a *responsible person* for a *regulated place* must make a Substance Management Plan (SMP) specific to the place. An SMP is a tool to assist entities identify and manage known and foreseeable risks specific to how they deal with regulated substances.

The SMP must comply with the requirements set out in the Departmental Standard – Substance management plans for medicines. The Standard covers all dealings that apply to medicines: manufacture, buy (give a purchase order), possess, supply (including sell, dispense, and give a treatment dose), prescribe or make a standing order, administer, and dispose of waste.

Schedule 17 of the MPMR specifies the list of regulated places that require an SMP and the person responsible for making the SMP for the type of place. For example, the responsible person for a community pharmacy is each pharmacist who owns the pharmacy.

For further guidance on SMPs refer to the Guide to developing a Substance management plan for medicines and the Substance Management Plans factsheet.

Prescriptions and dispensing

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; for example, an entry on a medication chart.

The initial date of the prescription is the date on which the prescription is written. Forward dating of prescriptions is **not** permitted under the MPMR.

From the date written, prescriptions for S2, S3 and S4 medicines are valid for **12 months**, while S8 medicine prescriptions are valid for **6 months**. This applies to both prescriptions for supply and prescriptions for administration.

A pharmacist must not dispense a prescription for a medicine unless the prescription is compliant with the requirements outlined in sections 86 to 88 of the MPMR.

A detailed reference guide on the requirements for compliant prescriptions can be found in the Writing Lawful Prescriptions factsheet.

A *paper prescription* includes both handwritten prescriptions and computer-generated prescriptions that have been printed. A paper prescription for dispensing must meet all the requirements specified in the MPMR for a lawful prescription, including a **handwritten signature**.

An *electronic prescription* is a prescription made in an electronic prescription management system (EPMS). An electronic prescription is **not** a computer-generated or handwritten paper prescription sent as a digital image, such as by fax or email, to a dispenser. For an EPMS to be compliant, it must be conformant with the requirements specified in Chapter 8, Part 1 of the MPMR (sections 184 to 193 MPMR), and the Departmental standard – Requirements for an electronic prescription management system.

A *written prescription* means any prescription in writing, and includes both electronic prescriptions and paper prescriptions, as well as medication chart prescriptions.

Dispensing monitored medicines and checking QScript

Monitored medicines are medicines potentially presenting a high risk of harm to patients as a result of misuse, abuse, diversion, substance use disorder and/or overdose. The list of monitored medicines is prescribed in Schedule 2, Part 4 of the MPMR.

Relevant practitioners required to check QScript are specified in Schedule 18, Part 1 of the MPMR, and includes pharmacists and intern pharmacists.

Under section 41 of the MPA, relevant practitioners are required to check QScript before:

- **prescribing** a monitored medicine for a person; or
- **dispensing** a monitored medicine for a person; or
- **giving a treatment dose** of a monitored medicine for a person.

In accordance with section 41(3) of the MPA, the requirement to check QScript does not apply if the relevant practitioner has a **reasonable excuse**; or if the monitored medicine dealing happens in circumstances prescribed by regulation to be **exempt** from the requirement. Exempt circumstances for checking QScript are listed in Schedule 18, part 1A of the MPMR.

A detailed reference guide on the responsibilities for pharmacists using QScript can be found in the Pharmaceutical professions and QScript factsheet.

When dispensing a monitored medicine, it is a requirement for the pharmacist to comply with the provisions of the Departmental Standard – Monitored Medicines. This is a separate requirement to accessing QScript and sets the minimum mandatory requirements that a pharmacist must comply with when dispensing a monitored medicine.

Amending prescriptions

A pharmacist is authorised to amend a written prescription under section 117 MPMR. The pharmacist may amend the prescription before dispensing the medicine by adding **additional information** to the prescription **to clarify the prescriber's direction**.

The pharmacist must:

- obtain consent to the amendment from the patient or person obtaining the medicine on their behalf; and
- have agreement to the amendment from the initial prescriber; and
- make the amendment in the way agreed by the prescriber and in a way that does not obscure any information on the prescription; and
- sign and date the amendment.

Oral prescriptions

A prescriber is authorised under section 92 MPMR to give an oral prescription for dispensing for an S4 or S8 medicine to a pharmacist.

If the pharmacist dispenses the medicine on the oral prescription, the prescriber must give the pharmacist a written prescription:

- within 7 days for an **S4 medicine**; or
- as soon as practicable, or no later than the end of the next business day for an **S8 medicine**.

If the original prescription is sent via post, the prescriber is deemed to have given the prescription to the pharmacist when it is put in the mail, not when the pharmacist receives it. Prescribers are recommended to use post tracking to prevent prescriptions going missing in the mail.

Image based prescriptions

A prescriber may send a digital copy of a paper prescription to a pharmacist by fax or as a digital image such as a photo or a scanned image under section 84 MPMR.

The prescriber must, as soon as practicable, send the original paper prescription to the pharmacist:

- **for S8 medicines**, no later than the end of the next business day after the digital image was sent; or
- **for other medicines**, no later than 7 days after the digital image was sent.

If the prescription is for a **diversion-risk medicine**[6], the prescriber must also annotate the prescription with the name of the pharmacy to which they are sending the prescription, the way it will be transmitted (e.g. by fax or email) and the date on which it is sent.

A prescriber may only send a digital image of a prescription to a pharmacy and must not provide this to a patient. **A digital image of a prescription provided by a patient to the pharmacist is not a lawful prescription.** Under section 115 MPMR, a pharmacist can only dispense a digital copy of a prescription from a prescriber or another pharmacist.

If a pharmacist sends a digital copy of a prescription for a diversion-risk medicine to another pharmacist under section 116 MPMR, the receiving pharmacist must make reasonable attempts to check whether the medicine has already been dispensed (e.g. by checking QScript). The sending pharmacist must send the paper prescription to the receiving pharmacist in the same timeframes as for prescribers described above.

Dispensing particular medicines

There are certain medicines that have additional requirements or considerations for prescribing or dispensing. Refer to the following factsheets for further guidance:

- Prescribing and dispensing unapproved medicinal cannabis
- Prescribing amfetamines and methylphenidate (psychostimulants)
- Schedule 8 MDMA and psilocybine

Dispensing interstate prescriptions

For a prescription to be dispensed in Queensland, a prescriber (i.e. either a Queensland prescriber or interstate prescriber) must ensure that the prescription meets the requirements of a lawful prescription under the MPA and MPMR.

For further detail refer to the Interstate prescriptions for dispensing in Queensland factsheet.

Selling without a prescription

Pharmacists are authorised to sell an S4 medicine without a prescription under specific circumstances. Refer to MPMR Chapter 5, Part 2, Division 3, Subdivision 3 (sections 155 to 160 MPMR) for supply and recording requirements.

Under MPMR Schedule 9, Part 1, Division 1, a pharmacist can also sell a medicine without a prescription under the EPA-Pharmacists, or as a pharmaceutical benefit under the Continued Dispensing Determination (Commonwealth legislation).

[6] see Schedule 2, Part 3 MPMR

Queensland Opioid Treatment Program (QOTP)

Pharmacists are authorised to dispense and administer QOTP medicines on a prescription from an authorised prescriber.

A detailed reference guide can be found in the Queensland Opioid Treatment Program: A key guide to legislative requirements under the *Medicines and Poisons Act 2019* guide.

Administering medicines

A pharmacist who is employed at a community pharmacy or private health facility, or is a health service employee, is authorised to administer medicines under MPMR Schedule 9, Part 1, Division 1A. This includes the authorisation to administer any S2 or S3 medicine, any medicine on a standing order, and an S4 or S8 medicine on a prescription or in accordance with the medicine's approved label (i.e. the dispensing label).

Compounding

Pharmacists are authorised to compound an S2 or S3 medicine for the treatment of a patient, or an S4 or S8 medicine to fulfil a prescription from a prescriber for a patient.

Under section 47 MPMR, a pharmacist must compound a medicine for human use in accordance with the Departmental standard – Compounding.

For compounding for animals on a veterinary prescription, refer to the *Agricultural and Veterinary Chemicals (Queensland) Act 1994*.

Other requirements

Storage and record keeping

Medicines must be stored in accordance with MPMR Chapter 8, Part 2. Under section 199 MPMR, medicines must be stored in an area where it is reasonably believed that a member of the public could not access the medicines without being seen by an employee at the place.

Section 224 MPMR describes the period of time that records must be kept and the way in which records must be kept. This does not apply to record keeping for pseudoephedrine, the requirements for which are described under section 162 MPMR, and the record must be kept in a way that complies with the Departmental standard – Pseudoephedrine recording.

Storage and record keeping for S8 medicines

Under section 197 MPMR, an S8 safe must be compliant with the Departmental standard – Secure storage of S8 medicines. A compliant S8 safe prevents the unauthorised removal of, or interference with, S8 medicines being stored at a place and minimises the risk that these medicines will be misused, abused or diverted.

Chapter 8, Part 2, Division 3 of the MPMR outlines the requirements for medicine registers, including both paper and electronic registers. Under section 211 MPMR, a pharmacist or assistant must make the record of the dealing in the medicine register as soon as practicable, but no later than 24 hours after the dealing. If an assistant makes the entry in the register, the authorised pharmacist supervising the assistant must also sign the entry under section 212 MPMR.

A detailed reference guide can be found in the Storage and record-keeping requirements for S8 medicines factsheet.

Under section 217 MPMR, the balance of the register must be reconciled against the actual stock on hand of S8 medicines in the safe at least **monthly** but may be carried out more frequently according to the SMP for that place.

Disposing of diversion-risk medicine waste

Pharmacists are authorised to dispose of and destroy waste from a diversion-risk medicine under section 147 MPMR. A medicine is destroyed when it has been rendered unusable and unidentifiable.

For further detail refer to the Disposal and destruction of diversion-risk medicine waste factsheet.

Reporting matters to the chief executive

There are a number of reporting obligations for health practitioners to notify the chief executive[7] under the MPMR, including the requirement to notify lost or stolen S8 medicines.

The Queensland Health web page Reporting medicines matters to the chief executive contains the specific forms that must be used for the purposes of notification.

Additional resources

In addition to the linked resources referred to in this factsheet, other relevant documents, resources and information sheets may be accessed from the Queensland Health site Factsheets and supporting documents.

For further information

Contact the Medicines Approvals and Regulation Unit

MARU@health.qld.gov.au

[7] The Director General, as chief executive of Queensland Health.

Appendix 1 – Commonly used terms

Term	Meaning
Deals	A person deals or is dealing with a medicine 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; and dispose of waste or otherwise use a medicine.
Dispense	Dispense means to sell the medicine to a person on prescription i.e. on the authority of a prescriber.
Diversion-risk medicine	The term used to collectively describe the group of medicines that present a higher risk for diversion. Diversion-risk medicines are listed in Schedule 2, Part 3 of the MPMR.
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 listed in Schedule 2, Part 2 of the MPMR.
Monitored medicine	The term used to collectively describe the group of medicines that are monitored via real-time prescription monitoring (QScript). Monitored medicines are listed in Schedule 2, Part 4 of the MPMR.
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. Restricted medicines are listed in Schedule 2, Part 1 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.

A term used in this fact sheet that is defined in the MPA or the MPMR has the meaning as stated in the MPA or MPMR.

Version control

Version	Date	ΗЂμ μ ĕυr
1	30 September 2021	New document.
2	30 June 2024	Updated to align with content more relevant to clinical practice now that legislative scheme is fully implemented.