Queensland Health

Key legislative requirements: midwives

Medicines and Poisons Act 2019

Introduction

From 27 September 2021, the *Medicines and Poisons Act 2019* (MPA) and the Medicines and Poisons (Medicines) Regulation 2021 (MPMR) and associated legislative instruments define the lawful actions in relation to medicines[1] (schedule 2 (S2), 3 (S3), 4 (S4) and 8 (S8)) of the Poisons Standard[2]) for therapeutic use in Queensland.

The MPA and MPMR can be accessed from the Queensland Legislation website via *In force legislation*– www.legislation.qld.gov.au.

The legislative instruments that have been approved by the chief executive[3] (Director General) to support the MPMR include departmental standards and extended practice authorities. These legislative instruments can be accessed from the Queensland Health website - Legislation, departmental standards and extended practice authorities

This information sheet has been prepared to provide an overview of the fundamental legislative requirements as it relates to midwives and endorsed midwives, as approved persons[4], to deal[5] (undertake regulated activities) with medicines.

Many of the requirements under the new Medicines and Poisons legislative scheme are similar to requirements under the repealed Health (Drugs and Poisons) Regulation 1996 (HDPR), however, the structure and the terminology of the new legislation have been modernised.

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The MPA introduces new terminology and modifies terms previously used in the repealed *Health Act 1937* and repealed Health (Drugs and Poisons) Regulation 1996 (HDPR). 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.

Appendix 1 details some of the terms commonly used including the meaning of 'the authorised way'. The 'authorised way' is a key concept in the MPA - it links a person's authorisation to perform particular regulated activities (dealings) with the specified conditions or requirements for performing the activity lawfully.

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[1] Section 11, *Medicines and Poisons Act 2019*.

[2] 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).

[3] The Director General, as chief executive of Queensland Health (section 10, *Public Services Act 2008)*, is responsible for administering the legislation portfolio set out under the Queensland Government's Administrative Arrangements Order.

[4] Section 13, MPMR.

[5] Section 18, *Medicines and Poisons Act 2019*.

Authorisation to deal with medicines

Schedule 7, Part 2 of the MPMR, sets out the types of activities (dealings), the medicines and the scope[6] for dealing with the medicines that may be carried out by 'approved persons' who are:

- midwives (Division 2),
- endorsed midwives (Division 3).

The MPMR specifies the circumstances, scope and supervision arrangements for when students may possess and administer medicines while training to obtain a qualification as a midwife[7].

Extended practice authority – midwives

The new scheme introduces an authority known as an 'Extended Practice Authority' (EPA). The MPA (section 232(4)) enables the Director General to make EPAs to state 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. In making an EPA, consideration has been given to a range of factors such as community need, any risks associated with the proposed dealing with the medicines, and the governance capability of the entity the approved person works for (see MPMR Chapter 9, Part 1).

The term EPA has a discrete meaning within the legislative scheme. 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 authorized under the EPA as 'extended practice'.

Schedule 7, Part 2 of the MPMR establishes the Extended Practice Authority - midwives. The EPA replaces the 'Drug Therapy Protocol – Midwives' made under the repealed HDPR.

Prescribing medicines – endorsed midwives

Schedule 7, Part 2, Division 3 authorises endorsed midwives to prescribe, orally or in writing, including electronic prescriptions[8] and medication chart prescriptions, to administer, dispense or give a treatment dose of medicine, except for restricted medicines[9] for the treatment of a person.

As such, endorsed midwives must comply with the requirements for prescribing medicines, as detailed in Chapter 4, Part 6 of the MPMR to ensure their prescribing activity is conducted in the 'authorised way'.

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[6] *Scope of dealing* may include the circumstance, purpose, extended practice authority or other matter for dealing with medicines.

[7] Schedule 13, Part 7 (trainee health practitioner) of the MPMR.

[8] Section 83 of the MPMR.

[9] Schedule 2, Part 1 of the MPMR.

When prescribing monitored medicines, endorsed midwives must comply with the Departmental standard -Monitored medicines.

> Endorsed midwives (as prescribed in Schedule 18, Part 1 of the MPMR) must check the monitored medicines database[10] (QScript) before prescribing or giving a treatment dose of a monitored medicine for a patient.

There are some important changes to the requirements for prescribing that endorsed midwives should be aware of:

- The MPMR now requires that all prescriptions for monitored medicines include the patients date of birth.
- A endorsed midwives may prescribe any Schedule 2, 3, or 8 medicine, other than a restricted medicine[11]
- A prescription for an S8 medicine must still 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 no longer needs to have the particulars handwritten on the prescription.
- Prescribers may not self-prescribe a high-risk medicine. High-risk medicines are listed in Part 2 of Schedule2 of the Regulation.
- A paper prescription 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.

More detailed information about the requirements for issuing prescriptions can be found in the information sheet *Writing lawful prescriptions*.

What is the difference between a prescription, a standing order and a clinical protocol?

A *prescription*[12] is instruction provided by a person who is authorised to prescribe, orally or in writing, including electronic prescriptions[13] and medication charts, to administer, dispense or give a treatment dose of medicine for the treatment of a person or animal. The MPMR includes requirements for a lawful prescription to administer a medicine such as a medication chart prescription (see Chapter 4 Part 6, Division 4). Like the HDPR, a prescriber who gives an oral prescription (e.g. a telephone order) for an S8 medicine must confirm that prescription in writing no later than the next business day (see section 100).

[10] Refer to Chapter 7, Part 2 of the MPMR.

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

[12] Part 6 of the MPMR.

[13] Section 83 of the MPMR.

A *standing order* is a document authorising a medicine to be administered or given as a treatment dose to a patient at a relevant institution[14] (aged care facility, hospital, prison or detention centre), *or* in stated circumstances at a particular services or places[15] (making other standing orders) that are not a relevant institution. An approved person who administers a medicine on a standing order must make and keep a record of the administration (see section 141 of the MMMR). For more information on making a standing order, see Chapter 4, Part 7, Division 2 of the MPMR.

A *clinical protocol*[16] is a type of standing order applying in relation to a specified class of approved persons e.g. a nuclear medicine technologist, performing a procedure or diagnostic test at a place.

Giving a treatment dose[17]

Midwives and endorsed midwives are authorised to give a treatment dose of medicines as detailed in Schedule 7, Part 2, Division 2 and 3 respectively. As such, they must comply with the requirements specified in Chapter 4, Part 9 of the MPMR to ensure this activity is conducted in the 'authorised way'. 'Giving a treatment dose' allows one or more doses to be given, for example, as a course of treatment.

A midwife or endorsed midwife who supplies (gives a treatment dose) of a S4 or S8 medicine to a patient must *attach a label to the medicine* [18]and *make a record of the supply*[19].

A midwife who gives a treatment dose to fill a prescription for an S4 or S8 medicine may supply the quantity prescribed even if less than a manufacturer's standard pack. In order to fill the prescription, the quantity of medicine may be packaged into another container.

S2 and S3 medicines are to be supplied to patients in the manufacturers packaging which contains the information about how to safely administer and store the medicine.

Expired prescriptions and medications

Midwives/endorsed midwives must not give a treatment dose or administer a medicine on a prescription that has expired[20]. 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*.

Expired medicines - A treatment dose of a medicine must not be given if the date on the container or label indicates the medicine is beyond its use by date.

[14] Chapter 4, Part 7, Division 2 of the MPMR.

[15] Section 104 of the MPMR.

[16] Section 101 of the MPMR.

[17] Distinct from 'dispense', to give a treatment dose of a medicine means to give one or more doses of the medicine to a patient to be taken at a later time.

[18] Section 134 of the MPMR.

[19] Section 136 of the MPMR

[20] Section 142 of the MPMR.

What is a substance management plan?

A substance management plan sets out how known and foreseeable risks associated with any dealing with a regulated substance are to be managed at the regulated place. A responsible person at a regulated place (Schedule 17, MPMR) must make a substance management plan that complies with the Department Standard – Substance Management Plans for medicines.

Midwives/endorsed midwives who are employed or contracted at a regulated place must comply with the requirements of the substance management plan approved for that place.

Other requirements

All midwives must comply with the storage, record-keeping, disposal and notification requirements (reporting to the chief executive) specified in the MPMR.

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 contained in Chapter 8 Part 2 of the MPMR and in the Departmental Standard: Secure Storage of S8 Medicines.

Disposal of medicine waste (including S8 medicine waste)

There are new arrangements for the destruction of S8 medicines in the MPMR. Unwanted or expired S8 medicines should not be sent to Forensic and Scientific Services, Queensland Health.

The MPMR stipulates the requirements for disposing of waste from diversion-risk medicines[21], including S8 medicines. Most medicine waste may be sent to an approved waste management contractor for high temperature incineration.

If the waste is from an S8 medicine, it must first be destroyed[22] (rendered unusable and unidentifiable) before being sent away for disposal. The specific requirements for destroying S8 medicines are detailed in the information sheet – *Disposal of S8 medicines waste.*

Reporting matters to the chief executive[23]

There are a number of reporting obligations for health practitioners to notify the chief executive[24] 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 suite of notification forms.

[21] Chapter 4, Part 11 of the MPMR.

[22] by an approved person and witnessed by another approved person, who are both authorised to dispose of diversion-risk medicines and destroy S8 medicines.

[23] The Director General, as chief executive of Queensland Health (section 10, *Public Services Act 2008)*, is responsible for administering the legislation portfolio set out under the Queensland Government's Administrative Arrangements Order.

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

Additional resources

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

For further information

Healthcare and Regulatory Approvals Unit - HARU@health.qld.gov.au

Appendix 1 – Commonly used terms

Term	Meaning
Authorised way	The 'authorised way' is a central tenet of the MPA and supporting regulations. A person carries out a regulated activity in the 'authorised way' if they are authorised to deal with medicines (regulated substances), they are authorised to deal with, and if they comply with the requirements to carry out the activity as specified under the MPA and MPMR. This includes compliance with Departmental Standards and Extended Practice Authorities, as legislative instruments, and if working at a regulated place, the Substance Management Plan.
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.
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. Medicines given to patients as treatment doses, whether given on a prescription or during a consultation with a prescriber, may not be sold.
Monitored medicines	Is the term used to describe a group of medicines (listed in Part 4 of Schedule 2 of the MPMR). The use of these medicines is monitored via real-time prescription monitoring (QScript).
Dispense	The term used in relation to a person selling a medicine to a patient on the authority of a prescriber.
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. The term 'issue' as defined in the repealed HDPR will not be used in the MPA framework.

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