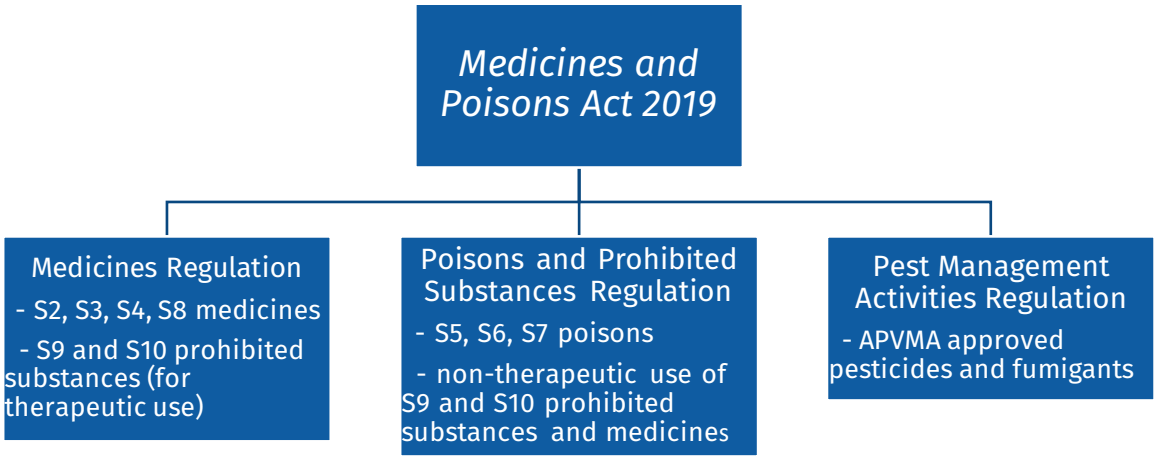
Medicines and Poisons Act 2019

Factsheet – current as at September 2021

Overview of the medicines framework



The Act introduces a new legislative framework for the regulation of **medicines**, poisons, prohibited substances, fumigants and pesticides (regulated substances) in Queensland.

This factsheet focuses predominantly on the **medicines** aspect of the framework.

General overview

As indicated by the diagram above, three regulations were enacted to support the Act:

- Medicines and Poisons (Medicines) Regulation 2021 (**MPMR**), which provides for medicines which are substances listed in Schedules 2, 3, 4 and 8 of the Commonwealth Poisons Standard (also known as the Standard for Uniform Scheduling of Medicines and Poisons or **SUSMP**), as well as prohibited substances (S9 and S10 substances) that are for therapeutic use; and
- Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021, which provides for poisons which are substances listed in Schedules 5, 6 and 7 of the SUSMP, as well as medicines and prohibited substances for non-therapeutic use, such as laboratory testing; and
- Medicines and Poisons (Pest Management Activities) Regulation 2021, which provides for pest management activities using pesticides and fumigants approved for use by the Australian Pesticides and Veterinary Medicines Authority.

Each of the regulations specify the requirements for the relevant substances and activities captured by the scheme. The regulatory framework applies to persons carrying out regulated activities with regulated substances and affects a broad range of stakeholders across

industries as diverse as agriculture, healthcare, pest management and veterinary services. The scheme has application to, for example:

- manufacturers and wholesalers of regulated substances;
- licensed retailers of medicines and poisons;
- trained health professionals with as of right authorities (expressly defined in the legislation) to deal with specific medicines in certain environments;
- pest management technicians and primary producers carrying out pest management activities; and
- landholders with approval to use regulated poisons.

The scheme also applies in a range of everyday settings to laypersons such as:

- having a prescription filled at a pharmacy;
- receiving life-saving medicines in a hospital setting; and
- enabling vulnerable people such as children, the elderly, and those with a disability, to receive medicines they require, when needed.

Relevantly, the scheme does not seek to regulate the everyday activities of consumers or carers, so long as these persons deal with regulated substances lawfully (e.g. filling a prescription at a pharmacy which was lawfully prescribed by a doctor).

Rather, the focus of the scheme is on regulating trained professionals (approved persons in the Act) and industry. Preserving the health and wellbeing of consumers of regulated substances, as well as the general public who may be exposed to these substances, is a key initiative of the scheme.

Key terminology used in the Act

Chapter 1 of the Act provides some key definitions that apply throughout the legislation, including for the following terms:

- substance;
- medicine;
- prohibited substance;
- regulated substance (i.e. a medicine, poison, prohibited substance, fumigant or pesticide);
- deals with a regulated substance (e.g. manufactures the substance, buys the substance);
- regulated activity (i.e. dealing with a regulated substance or a pest management activity); and
- manufacture, buy, possess, supply, sell, administer.

It is important to read the legislation carefully to ensure you understand what is meant specifically by these terms.

Authorisations under the Act

How is a person authorised under the Act?

Under the Act, the following persons are authorised to carry out a *regulated activity* with a *regulated substance*:

- an approved person (e.g. dentist, medical practitioner (GP and specialist), nurse, pharmacist);
- a person acting under an emergency order;
- the holder of a substance authority (i.e. a person holding a manufacturing licence, wholesale licence, retail licence, pest management licence, prescribing approval or general approval); and
- another person acting under a substance authority (e.g. an employee or representative of the holder of a substance authority or a student or volunteer for the holder of a substance authority).

What is an 'approved person'?

Schedules 3-15 of the MPMR prescribes the list of approved persons for the scheme. The list is detailed below:

MPMR schedule	Approved person
3	Aboriginal and Torres Strait Islander health professions
4	Dentistry professions
5	Emergency service providers
6	Medical practitioners and assistants
7	Nursing and midwifery professions
8	Ocular treatment professions
9	Pharmaceutical professions
10	Podiatry professions
11	Veterinary professions
12	Other health practitioners

MPMR schedule	Approved person
13	Workers at institutions and facilities
14	Suppliers and representatives
15	Miscellaneous

Under the MPMR, approved persons are authorised to carry out a regulated activity with a regulated substance because of their occupation, profession or the position they hold (as of right authorities).

Approved persons, for example, dentists, pharmacists and nurses using medicines in their work, or primary producers using certain pesticides or fumigants on their own property, will not be required to apply for a licence or general approval under the scheme to carry out specific regulated activities.

For each class of approved person, the MPMR expressly specifies and defines the permitted regulated activities and scope of practice for the different classes of approved persons, the medicines and poisons within this scope and any limits to the permitted regulated activities. For example, only a specialist medical practitioner may be authorised to prescribe a specific restricted medicine. The framework enables other prescribers to apply for a prescribing approval on an as needs basis.

What does 'the authorised way' mean?

A fundamental concept of the Act is that any activity performed with a regulated substance must be performed by a person who is authorised to perform the activity in the 'authorised way'. A person carries out a regulated activity with a regulated substance in the authorised way if:

- the person is authorised under section 54(4) (i.e. as an approved person), 57 (i.e. a person acting under an emergency order) or 62 (i.e. the holder of a substance authority or another person acting under a substance authority) to carry out the regulated activity with the regulated substance; and
- the person complies with the requirements prescribed for the person under section 91(1) for carrying out the regulated activity with the regulated substance (these requirements may be prescribed by regulation); and
- the person complies with any substance management plan that applies to the person.

The table below summarises a fundamental tenet of the Act, namely, that only authorised persons may deal with regulated substances in the authorised way.

Who	What	How
A person who is authorised: • approved person; • person acting under emergency order; • holder of substance authority; or • another person acting under substance authority.	May only deal with a regulated substance: • manufactures the substance; • buys the substance; • possesses the substance; • supplies the substance; • if the substance is a *medicine*: – administers the medicine; or – prescribes or makes a standing order for the medicine; • if the substance is a poison - applies the poison; • disposes of waste from the substance; • asks or directs another person to do something mentioned above.	In the authorised way: • the person is authorised under section 54(4) (i.e. as an approved person), 57 (i.e. a person acting under an emergency order) or 62 (i.e. the holder of a substance authority or another person acting under a substance authority) to carry out the regulated activity with the regulated substance; and • the person complies with the requirements prescribed for the person under section 91(1) for carrying out the regulated activity with the regulated substance; and • the person complies with any substance management plan that applies to the person.

Appendix 1 also summarises 'the authorised way' in diagrammatical format.

What is a substance authority?

The Act defines what a substance authority is, namely a:

- manufacturing licence;
- wholesale licence;
- retail licence;
- pest management licence;
- prescribing approval; or
- general approval.

A person is authorised to carry out a regulated activity with a regulated substance if the person:

- is the holder of a substance authority that authorises the holder to carry out the activity; or
- is stated or is a member of a class of persons stated, to be authorised under the authority to carry out the activity.

A substance authority is subject to standard conditions which are prescribed by regulation to apply to the substance authority, and any additional conditions which the chief executive of Queensland Health (or delegate) may decide.

Applications for the different types of substance authorities must be:

- made to the chief executive (or delegate) of Queensland Health;
- in the approved form; and
- accompanied by the fee prescribed by regulation.

What are the requirements for carrying out regulated activities in the authorised way?

A regulation may prescribe the requirements for a person, or a class of persons authorised under section 54(4) (an approved person), section 57 (a person acting under an emergency order) or section 62 (the holder of a substance authority or another person acting under a substance authority) in relation to carrying out a type of regulated activity with a regulated substance.

Substance management plans

The scheme introduces the concept of a substance management plan, which is a co-regulatory tool to assist substance authority holders to consider and manage known and foreseeable risks specific to regulated activities with regulated substances. The requirement for a substance management plan supports a risk-management system for regulated substances proportionate to the risk.

The scheme is outcomes-focused and substance management plans are required to contain minimum risk management, accountability benchmarks and governance criteria that must be established by certain persons and entities in their dealings with regulated substances.

Compliance, monitoring and enforcement

Are there any offence provisions?

Chapter 2 of the Act contains several offence provisions which predominantly relate to persons not carrying out activities in the authorised way. Under the Act, no offence will be committed if a person carries out the regulated activity in the authorised way, meaning, provided the person holds the necessary authority to carry out that activity.

A person also does not commit an offence under the Act if the person is authorised to carry out regulated activities under an emergency order. This may include circumstances where urgent action is needed to distribute medicines in response to the outbreak of an infectious disease, or to respond to a natural disaster which would otherwise jeopardise the safe storage of dangerous poisons.

What are some of the key compliance measures?

A range of compliance measures are made available under the scheme, including:

- providing for inspectors who have identified statutory powers and functions, to ensure compliance with the Act (these legislative powers are similar powers afforded to inspectors/authorised persons under other health legislation);
- enabling the chief executive of Queensland Health (or delegate) to take administrative action in relation to an authority under defined circumstances; and
- allowing the chief executive or an inspector appointed under the Act to issue a compliance notice in certain circumstances provided for in the Act.

What are some other monitoring and enforcement powers provided for in the Act?

The Act allows the chief executive to make:

- an emergency order;
- an emerging risk declaration;
- a recall order; or
- a public warning.

An emergency order may be made to take immediate action to manage the risk of significant harm or illness, or emergency situations where powers are needed to effectively manage the identified risk.

An emerging risk declaration may be made if there is a belief that an unscheduled substance or device used to apply or administer a substance poses a risk of injury or illness.

A recall order may be made if there is a risk of harm to persons or animals because of labelling, packaging, efficacy or other safety issues.

A public warning may be issued by the Minister, chief executive or chief health officer in the public interest to warn or inform the public about any person or persons who have:

- contravened the Act and against whom action is being taken; or
- committed any unlawful practices or offences against other relevant legislation.

Associated guidance documents

- Purposes of the Act - factsheet

Further information

For further information, contact the Healthcare Approvals and Regulation Unit:

- Email: HARU@health.qld.gov.au

Appendix 1 – the authorised way

Who A person who is authorised	What May only deal with a regulated substance	How In the authorised way
• approved person; • person acting under emergency order; • holder of substance authority; or • another person acting under substance authority.	• manufactures substance; • buys substance; • possesses substance; • supplies substance; – if the substance is a *medicine*, administers; or prescribes or makes a standing order for the medicine; • if the substance is a poison - applies the poison; • disposes of waste from the substance; • asks or directs another person to do something mentioned above.	• as an approved person; or • a person acting under an emergency order; or • a holder of a substance authority or another person acting under a substance authority to carry out the regulated activity with the regulated substance; and • the person complies with any requirements prescribed by regulation; and • the person complies with any applicable substance management plan

Notes to Appendix 1 – the authorised way

Who is an approved person?

MPMR schedule	Approved person
3	Aboriginal and Torres Strait Islander health professions
4	Dentistry professions
5	Emergency service providers
6	Medical practitioners and assistants
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8	Ocular treatment professions
9	Pharmaceutical professions
10	Podiatry professions
11	Veterinary professions
12	Other health practitioners
13	Workers at institutions and facilities
14	Suppliers and representatives
15	Miscellaneous

What is an emergency order?

An emergency order may be made by the chief executive (or delegate) to take immediate action to manage the risk of significant harm or illness, or emergency situations where powers are needed to effectively manage the identified risk.

What is a substance authority?

- manufacturing licence;
- wholesale licence;
- retail licence;
- pest management licence;
- prescribing approval; or

- general approval.

What is a regulated activity?

A regulated activity is dealing with a regulated substance.

What is a regulated substance?

A regulated substance is a **medicine**, poison, prohibited substance, fumigant or pesticide.

What is a substance management plan?

A substancement management plan for a regulated place, means a document setting out how known and foreseeable risks associated with any dealing with a regulated substance are to be managed at the regulated place.