Queensland Health Departmental Standard

Substance Management Plans for Medicines – version 1

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Queensland Government

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Version control

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1	NA	12 August 2021	27 September 2021

Contents

Preface

The *Medicines and Poisons Act 2019* (the Act) establishes a contemporary framework for the regulation of medicines, poisons, pesticides, fumigants and prohibited substances in Queensland.

This framework includes three regulations (the Regulations):

- Medicines and Poisons (Medicines) Regulation 2021
- Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021
- Medicines and Poisons (Pest Management Activities) Regulation 2021.

A requirement of the Act 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 these individuals and entities at the place to identify and manage known and foreseeable risks specific to how they deal with regulated substances. Where an SMP applies, a person must comply with the plan in order to carry out a regulated activity with a regulated substance in the authorised way.

An SMP must include the specific requirements listed in Chapter 4, Part 2 of the Act, including addressing the matters that are set out in regulation. The Medicines and Poisons (Medicines) Regulation 2021 (MPMR) section 173 specifies that an SMP for medicines must address the matters set out in this Departmental Standard.

Compliance with the SMP Standard will ensure that authorised persons employed by or contracted to the entity to deal with regulated substances at these regulated places hold the necessary competencies and authorities, appropriately control and deal with the substances and provide community assurance that regulated substances are managed in such a way that enhances public safety.

This Standard (Substance Management Plans for Medicines Standard) has been made by the Director-General, Queensland Health in accordance with section 233 of the Act.

Scope

The matters outlined in this standard are outcomes-focused and set minimum risk management, accountability and governance criteria that must be met for the entity operating at, or in connection with, the regulated place in their dealings with medicines. This performance-based approach allows the responsible person, who is prescribed by regulation, ensure local governance systems are developed and implemented to manage the risks unique to the circumstances at the regulated place. The entity may already have existing policies, procedures and accreditation documentation in place around their dealings at the regulated place, which may contribute content for an SMP.

As this standard is for the administration of the MPMR, this Standard is limited to medicine. The Standard covers all dealings that apply to medicines: manufacture, buy, possess, supply (including sell, dispense and give a treatment dose), administer, prescribe, make a standing order, and dispose of waste; it does not cover the dealing 'apply'.

Note: The Departmental Standard for Substance Management Plans for Regulated Poisons made for the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 applies to poisons and non-therapeutic uses of prohibited substances.

Application

Regulated places and responsible persons

A requirement of the Act is that a responsible person for a regulated place must prepare an SMP. For medicines, Schedule 17 of the MPMR specifies the list of regulated places that require an SMP and the person responsible for making the SMP for that type of place.

Dealings and regulated substances

A requirement of the Act is that an SMP must state the dealings and regulated substances to which the plan applies. As this Standard is made for the administration of the MPMR, any SMP made must include and apply to:

- all dealings relevant to the regulated place: manufacture, buy, possess, supply (including sell, dispense and give a treatment dose), administer, prescribe, make a standing order, and dispose of waste; and
- all regulated substances that are medicines which are used or likely to be used for a therapeutic purpose at, or in connection with, the regulated place.

Where a regulated substance is not used or a dealing not undertaken, then such a substance or dealing does not need to be included in the SMP for the regulated place.

Example 1: An SMP made for a place that manufactures only S4 medicines, does not need to include information relevant to S8 medicines.

Example 2: An SMP for a place that does not supply stock of medicines, does not need to include information relevant to supplying stock.

Review incidents

A requirement of the Act is that an SMP must be reviewed at the time specified by regulation. Under the MPMR section 174, an SMP must be reviewed:

a) as soon as practicable after a review incident happens in relation to the place; and

b) at least every 5 years after the day the substance management plan starts or if the plan is reviewed in any 5-year period after the plan starts, the day the plan was last reviewed.

A **review incident**, in relation to a regulated place, means "an incident stated to be a review incident for the place in the departmental standard 'Substance management plans for medicines' ".

For the purpose of section 174 of the MPMR, an SMP must be reviewed when any of the following review incidents occur:

1. There is a substantial change to the internal or external operations related to the dealings at, or in connection with, the place.

   Example 1: Change to management such as ownership, board of directors, corporate structure

   Example 2: Change in built environment such as new premises or buildings, renovations, installation of a new safe

   Example 3: Change in technology such as a new ICT system, purchasing or prescription software or security system

2. A non-compliant audit outcome results in new risks being identified or recommendations to modify how known and foreseeable risks related to dealings with medicines are managed.

   Example 1: An audit identifies changes in procedures are necessary to meet requirements in a new version of an Australian Standard applicable to compounding sterile medicines

   Note: An audit may be internal or external; may be an audit against the SMP or another audit

3. A systemic issue is identified as a result of:

   a) failure of risk-management systems for dealings in the SMP contributing to a critical or major incident, or

   b) a recurrence of undesirable incidents related to dealings with medicines, or

   c) a pattern of non-compliance with legislation, codes of practice or other requirements, including an SMP, across a substantial number of staff.

   Example 1: Serious patient infection linked to sterility breach in compounding cleanroom

   Example 2: Frequent loss or theft of medicines or loss or theft of large volumes

   Example 3: Frequent or significant issues with maintaining substance quality such as cold chain or biosecurity breaches.

Related legislation and documents

- *Medicines and Poisons Act 2019*
- Medicines and Poisons (Medicines) Regulation 2021
- Other Departmental Standards:
  - Departmental Standard – Secure storage of S8 medicines
  - Departmental Standard – Monitored medicines
  - Departmental Standard – Pseudoephedrine recording
  - Departmental Standard – Compounding
  - Departmental Standard – Requirements for an electronic prescription management system
  - Departmental Standard – Substance Management Plans for Regulated Poisons.
- Australian Code of Good Manufacturing Practice for the Feed Milling Industry [Code of Good Manufacturing Practice for the Feed Milling Industry (filesusr.com)]
- Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8 published by National Coordinating Committee on Therapeutic Goods (April 2011) [https://www.tga.gov.au/publication/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8]
- Australian Commission on Safety and Quality in Health Care Standard for Credentialing and Defining the Scope of Clinical Practice [Standard for Credentialling and Defining the Scope of Clinical Practice | Australian Commission on Safety and Quality in Health Care]
- Code of Conduct published by Medicines Australia (Edition 19, March 2020) [https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/20200108-PUB-Edition-19-FINAL.pdf]
- Health Service Directive: Credentialing and defining the scope of clinical practice [Credentialing and defining the scope of clinical practice (health.qld.gov.au)]
- Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-operation Scheme's: Guide to good practices for the preparation of medicinal products in healthcare establishments [https://picscheme.org/docview/3443]

Definitions

The terms used in this Standard have the same meaning as those in the Act and the MPMR. For ease of reference, some commonly used terms have been provided in the Glossary.

Requirements

The following sections specify the requirements for an SMP prepared under the MPMR.

Section 1 - General

Outcomes required	Minimum requirements
1.1. An SMP is easy to understand and includes when, where, how and to whom it applies	1.1.1. The SMP must state: • the day the SMP commences • the locations of the places where the SMP applies • the dealings and regulated substances (medicines) to which the SMP applies • the persons (staff) to whom the SMP applies. 1.1.2. The SMP must be written in such a way that it is easily understood by all relevant staff. 1.1.3. The SMP must be made available to all staff when it is made, including when materially revised. 1.1.4. The SMP must be a controlled document, specifying the version history, date of review(s), the name(s) of the person who completed any review and the reason/s for the review(s).
1.2. Known and foreseeable risks are identified and addressed	1.2.1. In the preparation (and review) of the SMP the following risks must be considered and addressed for each dealing in the SMP: • diversion/theft or other loss • fraud and tampering • expiry, cold chain breach, or other substance quality issue • improper or inappropriate use • public, patient, or environmental harm • staff having insufficient training, qualifications or experience to perform an activity • non-compliance with legislation or codes of practice.
1.3. An SMP is reviewed as frequently as necessary to maintain currency and effectiveness.	1.3.1. The SMP must reference or describe the processes/procedures for conducting a review of the SMP in the event a review incident occurs. 1.3.2. The SMP must describe or reference how a routine review of the SMP will be undertaken at least every 5 years to ensure that all known and foreseeable risks have been identified and appropriate controls are in place to mitigate those risks.

Section 2 - Manufacture

Outcomes required	Minimum requirements
2.1. Medicines manufactured are fit for purpose.	The SMP must describe or reference how 2.1.1. quality assurance is maintained throughout the manufacturing and/or compounding process to ensure the medicine is fit for purpose and free from contamination. 2.1.2. steps in the manufacturing process are only carried out by authorised personnel with the appropriate qualification/training/ experience 2.1.3. continuous and adequate supervision of the manufacturing and/or compounding process is maintained and recorded 2.1.4. adequate record-keeping is maintained to allow a clear audit trail and prevent tampering 2.1.5. the traceability of raw materials, unfinished and finished products will be sufficient to handle complaints, recalls and returns 2.1.6. processing, packing and labelling, including repacking and relabelling meet the applicable standards 2.1.7. plant and equipment, buildings and facilities are maintained to meet requirements for sanitation and calibration 2.1.8. materials, machinery, storage facilities, packaging and finished products are maintained to minimise contamination.
2.2. Access to the manufacturing area and storage areas for raw materials and finished products is controlled to prevent theft and tampering.	The SMP must describe or reference how: 2.2.1. only authorised personnel are granted access to the manufacturing area 2.2.2. medicines, both finished products and raw materials, are stored and handled in a secure manner.
2.3. Incidents, including potential incidents, are deterred, identified and reported in a timely manner.	The SMP must describe or reference how: 2.3.1. suspicious activity in and around the premises is detected and reported to the Queensland Police Service and/or relevant government authorities 2.3.2. incidents, including breaches or failures to achieve the outcomes required with respect to manufacturing, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.

Section 3 - Buy

Outcomes required	Minimum requirements
3.1. Purchase orders for medicines are made by appropriate persons or their delegates.	The SMP must describe or reference how: 3.1.1. only authorised personnel, with the appropriate position at the entity, can make or access and submit a purchase order for stock of medicine before or at the time of supply 3.1.2. delegations may be exercised, by whom and to what extent.
3.2. The stock received is secure and fit for purpose.	The SMP must describe or reference how: 3.2.1. goods received are recorded, secured and stored to maintain medicine quality/integrity 3.2.2. any damaged, unsuitable or expired medicines received are identified, quarantined and returned, destroyed or disposed of in a manner that is safe and secure.
3.3. Incidents, including potential incidents, are deterred, identified and reported in a timely manner.	3.3.1. The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to buying stock, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.

Section 4 - Possess

Outcomes required	Minimum requirements
4.1. Medicines are only accessible and possessed by appropriate persons.	The SMP must describe or reference how: 4.1.1. only appropriate persons, with respect to character and understanding of regulatory requirements, are employed, contracted or engaged by the entity to possess medicines 4.1.2. access to medicines is restricted to those appropriate persons with a need to access the medicine in order to minimise opportunities for diversion, theft and inappropriate use 4.1.3. adequate supervision is provided for persons who can only possess medicines under direct supervision or at the direction of an authorised person.
4.2. Medicines are stored in secure and appropriate storage.	The SMP must describe or reference how: 4.2.1. medicine stock is stored and handled in a secure, stable and safe manner considering the recommended storage conditions and separating and quarantining substances where necessary 4.2.2. any medicines that are expired, damaged or otherwise unsuitable for use are identified, separated and removed from use.
4.3. Recording and keeping of information enables traceability of medicines.	The SMP must describe or reference how: 4.3.1. the movement of medicines, both internal and external, is tracked and recorded, including the receipt, transfer, distribution, division, dilution, disposal or loss of medicine 4.3.2. reconciliation of medicines registers with stocks of medicines on hand will occur 4.3.3. records are to be kept so as to be retrievable, secure and tampering prevented.
4.4. There is compliance with relevant Departmental Standards.	4.4.1. The SMP must describe or reference how access and security measures for storage of S8s are compliant with the *Departmental Standard - Secure storage of S8 medicines*
4.5. Incidents, including potential incidents, are deterred, identified and reported in a timely manner.	4.5.1. With respect to the quantity, schedule and illicit value of medicines possessed, the SMP must describe or reference how suspicious activity in and around each storage location is detected and reported both internally and externally. 4.5.2. The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to possession, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.

Section 5 - Supply (of stock)

Outcomes required	Minimum requirements
5.1. Medicines are only supplied by appropriate persons.	The SMP must describe or reference how: 5.1.1. persons supplying medicine have the necessary qualifications and experience to maintain the quality, safety and security of medicines 5.1.2. persons supplying medicine are authorised to do so and adequate supervision of the supply is provided if applicable.
5.2. Medicines are only supplied to persons authorised to buy	The SMP must describe or reference how: 5.2.1. the authority of the person or entity directing or requesting the supply will be validated 5.2.2. medicines will only be supplied to persons authorised to buy or their nominated representative/delegate.
5.3. Medicines are delivered in a safe, secure and timely manner.	The SMP must describe or reference how: 5.3.1. medicines being transported will be protected from damage or deterioration from weather, light, heat etc., including at points of transfer and delivery 5.3.2. the integrity of the cold chain is maintained so supply of medicine is not compromised. 5.3.3. medicines being transported will be secured and tracked, to prevent unauthorised access and minimise the opportunity for theft or diversion.
5.4. Carriers engaged to deliver medicines are capable and reliable.	The SMP must describe or reference how: 5.4.1. a carrier engaged to deliver medicines will be assessed as capable to meet their obligations, including those in this Standard 5.4.2. the performance of a carrier engaged to deliver medicines will be monitored and reviewed.
5.5. Recording and keeping of information enables traceability of medicines.	The SMP must describe or reference: 5.5.1. how the movement of medicines (internal and external) is tracked and recorded; including the receipt, transfer, distribution, division, disposal or loss of medicine 5.5.2. how records are to be kept secure and tampering prevented 5.5.3. the checks and balances that are in place to ensure the right medicines are supplied to the right person 5.5.4. how traceability of medicines is sufficient to handle complaints, recalls and returns, and enable reconciliation to identify loss, theft or diversion.

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Outcomes required	Minimum requirements
5.6. Incidents, including potential incidents, are deterred, identified and reported in a timely manner.	The SMP must describe or reference how: 5.6.1. suspicious activity in and around the premises is detected and reported to the Queensland Police Service and/or relevant government authorities 5.6.2. incidents, including breaches or failures to achieve the outcomes required with respect to supply of stock, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.

Section 6 - Supply (for a person or animal)

Outcomes required	Minimum requirements
6.1. Medicines are dispensed, given as a treatment dose or otherwise supplied for a person or animal by appropriate persons.	6.1.1. The SMP must describe or reference how medicines are only supplied by authorised persons with the appropriate qualifications/training/experience. 6.1.2. The SMP must describe or reference how adequate supervision of supply is provided where necessary. 6.1.3. If medicines are supplied at the place under an extended practice authority, then the SMP must also describe or reference how: 6.1.3.1. persons engaged or credentialled to supply a medicine hold the necessary qualifications, registration and expertise and have demonstrated (and continue to demonstrate) the necessary competencies 6.1.3.2. the process to grant a credentialled scope of practice allowing a health professional to supply a medicine in accordance with a health management protocol meets the requirements of the current Health Service Directive: Credentialing and defining the scope of clinical practice or the current Australian Commission on Safety and Quality in Health Care Standard for Credentialing and Defining the Scope of Clinical Practice (where applicable for an extended practice authority). 6.1.3.3. the process to make and approve a health management protocol and to ensure health management protocols in use are current.
6.2. Medicines supplied for a person or animal are appropriately labelled.	6.2.1. The SMP must describe or reference how persons supplying medicines procure and apply the appropriate labels ensuring the relative requirements are met.
6.3. Records are kept of medicines dispensed, given as a treatment dose or otherwise supplied for a person or animal.	The SMP must describe or reference how: 6.3.1. records of medicines supplied for persons/animals are maintained to minimise the risk of diversion, overdose, or other negative outcomes 6.3.2. traceability of medicines is sufficient to handle complaints, recalls and returns, and enable reconciliation to identify loss, theft or diversion 6.3.3. records are secure and cannot be tampered with.

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Outcomes required	Minimum requirements
6.4. There is compliance with relevant Departmental Standards.	The SMP must describe or reference how: 6.4.1. records of pseudoephedrine sold are kept in compliance with the *Departmental Standard: Pseudoephedrine recording* 6.4.2. monitored medicines are supplied in compliance with the *Departmental Standard: Monitored Medicines*. 6.4.3. electronic prescription management systems meet the conformance and management requirements in compliance with the *Departmental Standard: Requirements for an electronic prescription management system*.
6.5. Incidents, including potential incidents, are deterred, identified and reported in a timely manner.	The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to dispensing, giving a treatment dose or other supply of medicines for a person or animal, will be identified in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.

Section 7 - Prescribe or make a standing order

Outcomes required	Minimum requirements
7.1. Only appropriate persons can prescribe or make a standing order for medicines.	The SMP must describe or reference how: 7.1.1. persons engaged or credentialled to prescribe a medicine hold the necessary qualifications, registration and expertise and have demonstrated (and continue to demonstrate) the necessary competencies 7.1.2. access by unauthorised persons to stationery, computers, devices, software etc. used for making a prescription is prevented.
7.2. Standing orders and prescriptions remain appropriate	7.2.1. The SMP must describe or reference how standing orders and longer-term prescriptions will be reviewed to ensure they remain appropriate for the circumstances and context and deliver improved health outcomes.
7.3. There is compliance with relevant Departmental Standards.	7.3.1. The SMP must describe or reference how prescribers are enabled to prescribe monitored medicines in compliance with the *Departmental Standard: Monitored Medicines* 7.3.2. The SMP must describe or reference how electronic prescriptions are generated, signed, sent, stored, amended, cancelled etc. in compliance with the *Departmental Standard: Requirements for an electronic prescription management system* 7.3.3. Electronic prescription management systems meet the minimum system requirements and are appropriately managed with clear policies/procedures for administration, operation, technical maintenance, audit etc. in compliance with the *Departmental Standard: Requirements for an electronic prescription management system*.
7.4. Incidents, including potential incidents, are deterred, identified and reported in a timely manner.	7.4.1. The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to prescribing medicines, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.

Section 8 - Administer

Outcomes required	Minimum requirements
8.1. Medicines are only administered by persons who are competent to administer medicines in the circumstances.	8.1.1. The SMP must describe or reference how medicines are only administered by authorised persons with the appropriate qualifications/training/experience. 8.1.2. The SMP must describe or reference how adequate supervision of administration is provided where necessary. 8.1.3. If medicines are administered at the place under an extended practice authority, then the SMP must also describe or reference how: 8.1.3.1. persons engaged or credentialled to supply a medicine hold the necessary qualifications, registration and expertise and have demonstrated (and continue to demonstrate) the necessary competencies 8.1.3.2. the process to grant a credentialled scope of practice allowing a health professional to administer a medicine in accordance with a health management protocol meets the requirements of the current Health Service Directive: Credentialing and defining the scope of clinical practice or the current Australian Commission on Safety and Quality in Health Care Standard for Credentialing and Defining the Scope of Clinical Practice (where applicable for an extended practice authority). 8.1.3.3. the process to make and approve a health management protocol and to ensure health management protocols in use are current.
8.2. Records are kept of medicines administered.	8.2.1. records of medicines administered are maintained to minimise the risk of diversion, overdose, or other negative outcomes 8.2.2. records of medicines administered can assist with the management of complaints, recalls and returns, and enable reconciliation to identify loss, theft or diversion 8.2.3. records are secure and cannot be tampered with.
8.3. Incidents, including potential incidents, are deterred, identified and reported in a timely manner.	8.3.1. The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to administering medicines, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.

Section 9 - Dispose

Outcomes required	Minimum requirements
9.1. Waste from medicines is disposed of appropriately by appropriate persons.	The SMP must describe or reference how: 9.1.1. S8 diversion-risk medicine waste is only disposed of by an authorised person and that adequate supervision/witnessing of the disposal is provided for as required 9.1.2. S8 diversion-risk medicine waste is to be destroyed so that it is rendered unusable, unrecognisable and unfit for human or animal use and incapable of growth or germination 9.1.3. diversion-risk medicine waste is to be disposed of so that access by an unauthorised person is prevented. 9.1.4. medicine waste is to be disposed of in a way that does not endanger a person, animal or the environment
9.2. Disposal of S8 diversion-risk medicine waste is recorded.	The SMP must describe or reference how: 9.2.1. disposed S8 diversion-risk medicine waste is recorded including the location, method of destruction, timing, personnel and any other relevant details 9.2.2. records are to be kept secure and are unable to be tampered with.
9.3. Incidents, including potential incidents, are deterred, identified and reported in a timely manner.	9.3.1. The SMP must describe or reference how incidents, including breaches or failures to achieve the outcomes required with respect to disposal of diversion-risk medicines waste, will be identified and reported in a timely manner to ensure a review is commenced and appropriate action taken to reduce or mitigate recurrence.

Glossary

Term	Meaning
Act	means the Medicine and Poisons Act 2019 (Qld)
administer	a medicine, means - (a) introduce a dose of the medicine into the body of a person or animal by any means; or (b) give a dose of the medicine to a person to be taken immediately. [Section 26 of the Act]
authority	means a substance authority or an approved person's authorisation. [Section 95 of the Act]
authorised site	means a site stated in a general approval (emergency first aid) [Schedule 16 Part 2 of the MPMR]
buy	a regulated substance, includes – Give a purchase order for the substance; and Otherwise attempt to obtain the substance, whether or not for consideration. [Section 22 of the Act]
cold chain	the system of transporting and storing medicines within safe temperature range for the medicine, usually +2°C to +8°C
credentialled	the practical experience, qualifications, professional awards and statements of competency issued by an authorised and recognised body that attest to a person's education, training and competence and relevant practical experience.

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Term	Meaning
deals	A person **deals** with a regulated substance if the person does any of the following activities – (a) manufactures the substance; (b) buys the substance; (c) possesses the substance; (d) supplies the substance; (e) if the substance is a medicine – i. administers the medicine; or ii. prescribes or makes a standing order for the medicine; (f) if the substance is a poison – applies the poison; (g) if the substance is a prohibited substance—otherwise uses the substance; (h) disposes of waste from the substance; (i) asks or directs another person to do something mentioned in any of paragraphs (a) to (g) [Section 18 of the Act]
dispense	a medicine, means sell the medicine to a person on prescription. [Section 25(2) of the Act]
dispose	of waste from a regulated substance, means discard, destroy or abandon the waste at a place. [Section 28 of the Act]
distribution	means a regulated substance is distributed or transferred between workers for the entity at or between the places [see Section 29 of the Act]
diversion-risk medicine	means a medicine that is a diversion-risk medicine. [Schedule 2 of the MPMR]
extended practice authority	means a document made by the chief executive: (a) stating the places or circumstances in which an approved person may deal with a regulated substance; or (b) imposing conditions on dealing with a regulated substance; or (c) requiring an approved person to hold particular qualifications or training to deal with a regulated substance. [see Section 232 of the Act]

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Term	Meaning
Good Manufacturing Practice	describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality.
governance	encompasses the system by which an organisation is controlled and operates, and the mechanisms by which it, and its people, are held to account. Ethics, risk management, compliance and administration are all elements of governance [Governance Institute of Australia].
health management protocol	a health management protocol is a document approved and dated by the chief executive of a Hospital and Health Service † or the Chief Executive Officer ‡ of a non-Queensland Health employing organisation that details the clinical use of medicines for services provided by an approved person who is authorised to deal with a medicine under an extended practice authority † refer to *Hospital and Health Services Boards Act 2011* ‡ Chief Executive Officer means the highest ranking executive or administrator in charge of the management of an organisation
manufacture	a regulated substance – means carry out any activity using any substance for the purpose of making the regulated substance; and Includes any process or step undertaken to produce the regulated substance or to prepare the regulated substance for supply to the public or a person, including for administration to an animal. [Section 21 of the Act]
medicine	is – a substance to which the Poisons Standard, schedule 2 applies (an S2 medicine); or a substance to which the Poisons Standard, schedule 3 applies (an S3 medicine); or a substance to which the Poisons Standard, schedule 4 applies (an S4 medicine); or a substance to which the Poisons Standard, schedule 8 applies (an S8 medicine). [Section 11 of the Act]
monitored medicine	means a medicine specified in Schedule 2 Part 4 of the MPMR. These are medicines identified by Queensland Health as potentially presenting a high risk of harm to persons as a result of misuse, abuse, diversion, substance use disorder and/or overdose. [Schedule 1 of the Act]

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Term	Meaning
possess	a regulated substance means to have custody or control of the substance. To remove any doubt, it is declared that a person may possess a regulated substance jointly with another person. [Section 23 of the Act]
prescribe	means direct a person, orally or in writing, to administer, dispense or give a treatment dose of the medicine for the treatment of a person or animal. [Schedule 1 of the Act]
prescriber	means a person who, under the MPMR, is authorised to prescribe a medicine for a patient or an animal.
regulated activity	is – (a) a dealing with a regulated substance; or (b) a pest management activity or asking or directing another person to carry out a pest management activity. [Section 20 of the Act]
regulated place	means a place: where a dealing happens, or is proposed to happen, with a regulated substance; and prescribed by Regulation to be a regulated place. [Section 92 of the Act]

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Term	Meaning
regulated substance	is a medicine, poison, prohibited substance, fumigant or pesticide and includes a substance listed in any of the following schedules of the current Poisons Standard within the meaning of the Therapeutic Goods Act 1989 (Cwlth), section 52A(1) — Schedule 2 – Pharmacy medicine Schedule 3 – Pharmacy only medicines Schedule 4 – Prescription only medicine Schedule 5 – Caution Schedule 6 – Poison Schedule 7 – Dangerous poison Schedule 8 –Controlled drug Schedule 9 –Prohibited substances Schedule 10 – Substances of such danger to health as to warrant prohibition of sale, supply and use. [see Section 17 of the Act]
responsible person	for a regulated place, means the person prescribed by regulation to be the responsible person for the regulated place. [Section 92 of the Act]
review incident	in relation to a regulated place, means an incident stated to be a review incident for the place in the departmental standard 'Substance management plans for medicines. See page 6 of this Standard. [Section 174 of the MPMR]
secure area	means an area or receptacle in an area that is locked or otherwise secured in a way that is designed to prevent access to the area or receptacle by a person who is not authorised to access the area or receptacle. [Schedule 22 of the MPMR]
sell	a regulated substance includes attempt to sell the substance or make the substance available for sale. [Section 25 of the Act]
specified pharmacy	means - (a) a community pharmacy operated by a friendly society or the Mater Misericordiae Health Services Brisbane Limited; or (b) a pharmacy supplying medicines to inpatients of a hospital. [Schedule 17 of the MPMR]

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Term	Meaning
standing orders	for a medicine, means a document authorising the medicine to be administered or given as a treatment dose at a stated place or in stated circumstances. [see Schedule 1 of the Act] A clinical protocol is a type of standing order [Section 101 of the MPMR]
stock	means— (a) a regulated substance that is intended for supplying a place or a person who is authorised to carry out a regulated activity with the substance; or (b) a regulated substance that is not sold or dispensed to a particular person. [Schedule 1 of the Act]
substance 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, or in connection with the regulated place. [Section 92 of the Act]
supervision	by a supervisor of another person, means the oversight by the supervisor of the dealings of the other person for – (a) directing, demonstrating and monitoring the dealings; and (b) checking the other person's level of competency for the dealings. [Schedule 22 of the MPMR]
supply	a regulated substance- means to sell or give the substance to a person. However, supply, a regulated substance, does not include– (a) if the substance is a medicine–administer the substance; or (b) if the substance is a poison–apply the substance; or (c) dispose of waste from a substance. [Section 24 of the Act]
treatment dose	to give a treatment dose of a medicine, means - to give one or more doses of a medicine to a person to be taken by a particular person, or administered to an animal, at a later time. [Section 25 of the Act]