

Procedures and protocols for medicines management

1. Purpose of this guideline

The *Health (Drugs and Poisons) Regulation 1996* (Regulation) regulates the access, storage and use of scheduled medicines in Queensland. Section 18 of the Regulation allows the Chief Executive to grant an endorsement (approval) for the use of scheduled medicines and impose conditions that apply to the approval. To demonstrate suitability to hold an approval, an applicant must satisfy Queensland Health that sufficient governance is in place to ensure that scheduled medicines will be managed effectively and safely. This guideline has been prepared to assist applicants to develop and implement documented processes and procedures relevant to scheduled medicines.

2. Scope of guideline

The information in this guideline may assist applicants who propose to use scheduled medicines for:

- *Emergency first aid*
- *Animal care and management*
- *Treatment of acute health conditions at isolated locations*
- *Immunisation or sexual and reproductive health programs*
- *Other therapeutic purposes*

Importantly, this guideline is only intended to provide general information to applicants. Applicants should review the relevant guideline and application form to determine what is specifically required, and should also consider their own circumstances, the location and nature of their intended operations, and the risks involved.

3. Risks to be addressed

To demonstrate suitability to hold an approval, applicants must show how they intend to meet the regulatory requirements and any conditions likely to be placed on an approval. In particular, applicants must demonstrate how they will ensure:



- scheduled medicines will only be obtained from, issued to, and used by, authorised persons
- persons possessing, administering and supplying scheduled medicines have sufficient training/knowledge, and are of good character
- medicines will be fit for purpose – not spoiled, expired or otherwise contaminated
- errors in administering or supplying scheduled medicines will be minimised
- risks of diversion, theft and misuse of scheduled medicines will be mitigated
- scheduled medicines will be destroyed appropriately.

4. Procedures and protocols for medicines management

Applicants seeking to use scheduled medicines under an approval should have established procedures and protocols to manage the likely risks involved with their intended activities. All procedures and protocols must be approved by the company directors, specialist medical practitioner/veterinary surgeon, panel of clinicians and/or other qualified persons, as appropriate. These documents may be grouped together, or documented separately, however, each document must clearly state:

- who prepared, reviewed and approved the document
- the date the document was prepared and the version number of the document
- changes from any previous versions of the document
- when the document will next be reviewed
- who the procedure or protocol applies to.

At a minimum, applicants should have in place procedures and protocols covering each of the following areas that detail how the desired outcomes (listed below) are likely to be achieved.

4.1. Organisational and Operational Management

Procedures and protocols should cover ordering medicines; the movement of medicines around the organisation; storage and security of medicines; record keeping and reporting; and auditing.

Purchasing/Obtaining

- Only scheduled medicines authorised under an approval are purchased, and in appropriate quantities;
- Only persons nominated by the organisation, and authorised under an approval, may purchase scheduled medicines;
- Purchase orders for scheduled medicines must be compliant with the legislative requirements;
- Scheduled medicines are only allowed to be received by persons authorised under an approval.

Storage

- storage of scheduled medicines complies with all relevant legislative requirements;
- scheduled medicines are stored in a way to deter and prevent unauthorised access;
- personnel only have access to those scheduled medicines for which they are authorised under an approval;
- the integrity of scheduled medicines is maintained;
- loss or theft of scheduled medicines can be easily identified and managed.

Possession/Issuing

- scheduled medicines are only issued to, and possessed by, authorised persons;
- the movement of scheduled medicines can be tracked, and their whereabouts identified, at all times.

Disposal

- disposal of scheduled medicines is undertaken in compliance with legislative requirements;
- expired or unused scheduled medicines are disposed of in a way that prevents unnecessary or dangerous exposure to people, animals or the environment;
- disposal of scheduled medicines is only undertaken by authorised persons.

Records/reporting

- all record keeping and reporting complies with legislative requirements;

- records are kept allowing traceability of scheduled medicines – obtaining, storing, issuing, administering, supplying, disposing;
- records kept are sequential, legible, and signed and witnessed, where necessary;
- the security and integrity of all records are maintained, and entries may only be amended by the person who made the original entry;
- all record keeping and reporting must comply with legislative requirements;
- notifications of operations, loss/theft of medicines etc. are done as required and in a timely manner.

4.2. Suitably qualified personnel

Procedures and protocols should cover engagement of personnel; background checks; accreditation of training, knowledge and skills; continuing professional development; and remedies for misuse of medicines.

Character and performance

- only suitable, responsible adults are employed and authorised to access and use medicines;
- appropriate supervision is provided to ensure compliance with legislative requirements and protocols;
- appropriate action is taken by the organisation for misuse of scheduled medicines, or breaches of protocols.

Training/Qualifications

- personnel have obtained the minimum qualifications required for the relevant regulated activity, and are registered under the Health Practitioner Regulation National Law (Queensland) where required;
- training is provided or promoted to ensure the competency, skills and knowledge of personnel are maintained;
- credentialing is undertaken by a specialist medical practitioner, veterinary surgeon or registered training organisation, as appropriate.

4.3. Clinical practice

Procedures and protocols should cover clinical use of medicines; supervision and oversight; medical instructions and authorisations; labelling; incident reporting; and clinical audit and review.

Administration

- scheduled medicines are only used by authorised persons with the necessary qualifications and training;
- scheduled medicines are only used for their intended and approved purpose, and are used effectively;
- off-label use of scheduled medicines (where authorised) must be accompanied by a record of informed consent from the patient;
- sufficient information is readily available on each scheduled medicine authorised under the approval, including:
 - name of the schedule medicine;
 - form of the scheduled medicine;
 - strength of the scheduled medicine;
 - route of administration of the scheduled;
 - dosage of the scheduled medicine;
 - indications and contraindications for the use of the scheduled medicine;
 - precautions relevant to the scheduled medicine;
 - side effects of the scheduled medicine; and
 - any other relevant information – including who is authorised to use the medicine and whether a doctor/veterinary surgeon’s instruction is required (for example, see Appendix 1 of this guideline);
- only scheduled medicines listed in the approval are included to avoid confusion and unauthorised use of medicines;
- medical advice is readily available and obtained, where required;
- details of administration of the scheduled medicine, including patient details, are recorded.

Supply

- scheduled medicines are not supplied unless authorised under an approval;
- scheduled medicines supplied are labelled correctly (including any warnings) and in accordance with legislative requirements;
- details of supply of the scheduled medicine, including patient details, are recorded.

Oral and written instructions

- personnel have a full understanding of when an instruction to administer a medicine is required to be obtained from the medical practitioner/veterinary surgeon – for example, which scheduled medicines require this, and under what circumstances;
- personnel have a full understanding of the process involved to contact the medical practitioner/veterinary surgeon – for example, when and how to contact them, and what to do if contact is unable to be made;
- legislative requirements relevant to oral and written instructions must be complied with – all oral instructions must be followed by a written instruction within specified timeframes.

Contact details

For further information on applications, including supporting documentation required, please contact:

Healthcare Approvals and Regulation Unit (HARU)

Tel: 07 3708 5264

Email: HARU@health.qld.gov.au

www: <http://www.health.qld.gov.au/system-governance/licences/medicines-poisons/approvals-authorities>

Appendix 1: Example information included in a Clinical Practice Protocol

Legend

- Administration permitted
- ▲ Administration permitted if additional training/qualification completed
- ◆ Administration permitted on a doctor's instruction
- Administration permitted on a doctor's instruction if additional training/qualification completed
- ✗ Administration not permitted

Drug type	Form of drug	Qualified First Responder	Qualified Paramedic
Adrenaline (pre-loaded syringe)	Injectable	●	●
Amiodarone	Injectable	✗	■
Atropine	Injectable	✗	◆
Glucagon	Injectable	✗	●
Glyceryl trinitrate	Tablet or pump spray	◆	●
Lignocaine	Injectable	✗	●
Methoxyflurane	Inhalation	■	●
Midazolam	Injectable	✗	◆
Naloxone	Injectable	▲	●
Nitrous oxide	Inhalation	✗	●
Salbutamol (metered-dose inhaler)	Inhalation	▲	●
Salbutamol (nebulised)	Inhalation	✗	●

DRUG NAME (Generic Name)**SCHEDULE 3****FORM**

Ampoule – ...mg/1mL

ROUTE OF ADMINISTRATION

Intramuscular (IM)

Intravenous (IV)

INDICATIONS

- **Condition A** (extra information if necessary)
- **Condition B** (extra information if necessary)

CONTRAINDICATIONS

- **Absolute** contraindications:
 - Patient under 18 years
- **Relative** contraindications:
 - History of...

PRECAUTIONS

- The medicine is... which can cause...

SIDE EFFECTS

- Allergic reaction including...

DOSE AND ADMINISTRATION

1. Adult dosages:
 - Loading dose of ...mL
 - Maintenance dose of ...mL/hour patient weight < 70 kg; ...mL/hour for patient weight ≥ 70 kg
2. Paediatric dosages:
 - NOT AUTHORISED

OTHER INFORMATION

- Onset (IV) ~ 30 seconds
- Duration (IV) 3-6 hours
- DO NOT FREEZE

AUTHORISATION

Qualified First Responder	✘
Qualified Paramedic	◆