

Guideline - Approvals to use scheduled medicines for treatment of acute health conditions at isolated locations

H DPR approvals for registered nurses at mine sites, island resorts and other isolated

1. Purpose of this guideline

This guideline has been prepared to provide information for those seeking to apply for an *Approval to use scheduled medicines for treatment of acute health conditions at isolated locations* (**isolated location approval**) under section 18 of the *Health (Drugs and Poisons) Regulation 1996* (**Regulation**). This guideline details the scope of this class of approval, the information required to apply and expectations of how scheduled medicines are to be managed if granted an approval.

2. Scope of this class of approval

Isolated location approvals are intended to allow the use of scheduled medicines to treat acute health conditions at isolated locations, such as **mine sites** and **island resorts**. An approval may only be granted to an organisation either responsible for the operations at the isolated location, or to an organisation providing contract services to such an organisation.

Approvals are to allow the site senior executive, chief executive or other similar person nominated by the organisation, to purchase the medicines and issue the medicines to registered nurses to provide treatment of acute health conditions in conjunction with a nominated doctor. As approvals centre on the relationships between the doctors / registered nurses, it is up to the nominated doctors to determine which medicines are required, based on the location's circumstances and the competencies of the registered nurses.

3. Applying for an approval

Applications for an *Approval to use scheduled medicines for treatment of acute health conditions at isolated locations* must be made using the [application form](#). Applications and supporting documents can be sent:

By post: The Chief Executive, Queensland Health
c/o Healthcare Approvals and Regulation Unit
Locked Bag 21
Fortitude Valley QLD 4006

Via email: HARU@health.qld.gov.au

Applicants must demonstrate their suitability to hold an approval, by providing supporting documentation on the governance that is in place to ensure that medicines will be managed and used appropriately. All documents provided must be dated and endorsed and, where relevant, signed and version controlled. Applicants should refer to the Guideline: [Procedures and Protocols for Medicines Management](#) for guidance in developing supporting documentation.

3.1. Information required

Organisations applying for an isolated location approval must provide details of:

- the organisation including names and details for all directors of the organisation;
- the location(s) where treatment is to be provided, including details of the storage of all medicines;
- the persons nominated to be responsible for the management and control of scheduled medicines at the isolated location(s);
- a doctor(s) employed, contracted or otherwise engaged by the organisation to provide governance and support to the registered nurse(s) providing treatment, including instructions to administer and supply medicines.

3.2. Supporting documents required

To support assessment of suitability to hold an approval, organisations must provide at a minimum, the following supporting documentation:

- a copy of the **current company extract** from the Australian Securities and Investments Commission (ASIC) – not a *company summary* from the ASIC register;
- **certified** proof of identity documents for all directors of the organisation and the person/s nominated to be responsible for the management and control of scheduled medicines;
- a declaration by one of the directors of the organisation that there is a binding arrangement between the organisation and the (named) nominated doctor(s), with the declaration detailing what role each of the nominated doctor(s) will have;
- if providing contract nursing services (to the organisation responsible for the operations at the isolated location), a letter to your organisation confirming the contract, signed by one of the directors from the contracting organisation.

Organisations that have previously held an approval from Queensland Health may also be asked to sign a statutory declaration that all regulatory requirements and all conditions on their approval have been complied with.

4. What to expect after making an application

In determining the suitability of an applicant, Queensland Health assesses all information provided with an application including background, skills and qualifications of persons who will have access to medicines, proposed activities and locations where scheduled medicines are to be used and stored, and the documented governance arrangements in place.

All applications are assessed separately on their own merit, and there is no guarantee that an approval will be granted to any applicant.

5. What to expect if an approval is granted

5.1. What this class of approval typically authorises

An *Approval to use scheduled medicines for treatment of acute health conditions at isolated locations* granted to an organisation typically authorises:

- a doctor(s), nominated by the approved organisation (approval holder), to purchase scheduled medicines on behalf of the approved organisation;
- a senior person(s), nominated to be responsible for the management and control of scheduled medicines at the approved organisation, to possess and issue the purchased medicines to a registered nurse(s) within the organisation for the purpose of providing treatment of acute health conditions; and
- a registered nurse(s) to possess, administer and supply specific scheduled medicines for the purpose of providing treatment of acute health conditions in accordance with the approved organisation's clinical practice protocols and, where required, on the instruction of the nominated doctor – see **Appendix 1** of this guideline for details.

5.2. What this class of approval typically *does not* authorise

An isolated location approval typically **does not** authorise:

- the use of any scheduled medicines obtained under the approval for ongoing primary health care;
- an approval holder providing medical treatment at sites that hold a Royal Flying Doctor Service (RFDS) Medicine Chest (an outpost under the Regulation);
- the approval holder to provide treatment from a location where Schedule 2 medicines may be sold under a general poisons licence.

6. Responsibilities of approval holders

Approval holders are expected to have sufficient governance and control over the purchase, storage and use of scheduled medicines to minimise the risk of harm to the public, by ensuring that medicines are only accessed and used by authorised persons and are used safely and effectively.

The Regulation prescribes how scheduled medicines must be purchased, stored and used, as well as requirements for documents that must be kept and for how long. In addition to these requirements, a decision-maker may impose conditions on an approval that must be followed. These conditions are imposed to manage risks associated with the possession and use of scheduled medicines.

As general guidance, to support compliance if granted an approval, applicants should take note of the following mandatory requirements and conditions commonly placed on an isolated location approval.

6.1. Mandatory requirements

Purchasing/Obtaining

- Only scheduled medicines specified in the approval may be purchased. The medicines to be used by the approved organisation must only be obtained:
 - on a written purchase order that complies with the Regulation¹; and
 - from a licensed drug wholesaler.
- Any purchase order made must be kept for a period of at least two (2) years; and produced to an authorised inspector upon request.

Possession/Issuing

- Persons are only authorised to have access to those scheduled medicines listed in the approval relevant to their position/qualification to perform their legitimate duties.

Instructions to administer

- For an oral instruction to administer any Schedule 8 medicine, the nominated doctor must provide a written instruction within 24 hours. If a written instruction is not provided within 24 hours, the registered nurse given the instruction must notify the local Public Health Unit within 48 hours of being given the oral instruction.

Storage

- Schedule 8 medicines (S8s) must be kept in a receptacle that complies with Appendix 6 of the Regulation, or a place assessed by an inspector appointed under the *Health Act 1937* (Qld) as being as secure as that prescribed in Appendix 6 of the Regulation. The keys or combinations to the approved receptacles or secure places must remain in the possession of the persons who are authorised to possess S8s under the approval;
- Schedule 4 medicines (S4s) must be stored in cupboards, drawers, storerooms or other locations to which the public (and persons without authorisation) do not have access;
- Schedule 2 medicines (S2s) and Schedule 3 medicines (S3s) must be stored so that they are inaccessible to persons not authorised under the approval.

Disposal

- Expired or unused S8s must be sent to [Forensic and Scientific Services](#) to be destroyed appropriately.
- A person must not dispose of S4 medicines unless the person is authorised to dispose of the medicine.

¹ An example of a purchase order that is compliant with the Regulation is provided on the [Queensland Health website](#).

6.2. Conditions commonly placed on emergency first aid approvals

In granting an approval, a decision-maker may impose conditions on the approval that **must** be followed. Conditions that are commonly imposed on isolated location approvals to manage risks associated with the possession and use of scheduled medicines generally cover the areas listed below. These apply **in addition** to the mandatory requirements described in section 6.1 above.

Governance

- Approved organisations must have documentation describing the organisation's processes that demonstrate the organisation's responsibility, accountability and due diligence relevant to the management of scheduled medicines, including:
 - operational standards with details of the arrangements proposed to be used for obtaining oral or written instructions to administer or supply medicines; and
 - clinical audit and effectiveness assessments, including processes relevant to:
 - obtaining, issuing, administering and supplying scheduled medicines;
 - storage of scheduled medicines;
 - recording transactions relevant to scheduled medicines; and
 - system monitoring after any adverse, or potential adverse, incident.
 - risk management arrangements and processes;
 - education and training requirements for new and continuing employees to maintain standards of professional practice;
 - information management, including complying with recording and reporting requirements.

Nominated doctor(s)

- The approved organisation must enter into and maintain binding arrangements with a nominated doctor to ensure obligations under the approval are met. These arrangements must include that:
 - the nominated doctor is responsible for signing purchase orders for the medicines to be used under the approval; and
 - the nominated doctor must be contactable to provide instructions to persons providing treatment under the approval at any time nursing services are being provided.
- Where the binding arrangements between the approved organisation and nominated doctor are materially amended, cancelled, or replaced by new arrangements (with the same or an alternative nominated doctor) the organisation must notify Queensland Health, via email to HARU@health.qld.gov.au, within seven (7) days of the amendment(s).

Purchasing/Obtaining

- The medicines to be used by the approved organisation must only be obtained on a purchase order signed by a nominated doctor.

Possession/Issuing

- Scheduled medicines must only be issued by a nominated person to a registered nurse who is authorised to administer or supply the scheduled medicine.

Storage

- When any scheduled medicines are being transported in a vehicle, they must be stored in an area of the vehicle which is kept locked and is not visible from outside of the vehicle. The key to the locked area of the vehicle must remain in the personal possession of the person in charge of the scheduled medicines who is authorised under the approval to possess the scheduled medicines.
- Appropriate cold chain management of perishable medicines must always be maintained.

Administration/Supply

- Registered nurses may only administer or supply those scheduled medicines listed in the approval and in accordance with the corresponding conditions, if any – see **Appendix 1** of this guideline for details of medicines typically authorised and the conditions typically applied.
- Standing orders are not to be used for the administration or supply of any scheduled medicine.
- Schedule 8 medicines are not approved for supply.
- Medicines being supplied must be labelled to the same standards as required under the Regulation, i.e.:
 - “**KEEP OUT OF REACH OF CHILDREN**” in RED on a background of contrasting colour and in bold-faced sans serif capital letters with a face depth of at least 1.5 mm;
 - “**EMERGENCY SUPPLY**” in a colour contrasting with the background colour and in bold-faced sans serif capital letters with a face depth of at least 1.5 mm;
 - the approved name of the medication; or the trade name of the medication; or the name of each medicine, present in the medication;
 - the strength of, and quantity or volume of, the medication supplied;
 - directions about the use of the medication;
 - the date of supply;
 - the expiry date of the medication;
 - the name of the registered nurse who supplied the medication;
 - the name of the location at which it was supplied; and
 - if necessary, the warning statements specified in the [Regulation section 198\(3\)\(i\) and section 276\(3\)\(i\)4.](#)

Disposal

- Expired or unused scheduled medicines (other than S8s) must be given to a pharmacist to be destroyed appropriately.

Record keeping/Reporting

- Approved organisations must maintain a register that allows traceability of all scheduled medicines, by recording the following information for all incoming and outgoing stock of scheduled medicines (including any internal transfers if relevant):
 - the date of dealing (e.g. obtaining, issuing/transferring, administering, supplying, disposing) with the medicine;
 - name, strength, form and quantity of the scheduled medicines being dealt with;
 - the nature/type of the dealing;
 - the name and position/qualification of the person dealing with the medicine;
 - the location where the medicine is being dealt with;
 - for administration/supply:
 - the name of the patient; and
 - where applicable, name of the doctor providing the instruction authorising administration or supply of the scheduled medicines, and the date and time the scheduled medicine was administered or supplied;
 - for disposal, the name and position of the person who authorised the disposal;
 - if the register is kept on paper, the signature of the person dealing with the medicine, or if the register is kept electronically, a unique identifier of the person dealing with the medicine;
 - balance of stock on hand (at each location).
- Entries in the register must be made in the order in which the transactions occur. Records must show a progressive balance of used and remaining stock, and are required to be kept for at least two (2) years from the date of the last entry. Separate pages must be used for each different class or strength of scheduled medicine, and the pages must be numbered chronologically.
- An incorrect record entry may only be corrected by the person who made the entry. This must be corrected by making a signed and dated marginal note or footnote giving the correct details.
- At **reasonable** intervals of not more than one (1) month, the stock of scheduled medicines must be checked by an authorised person to ensure that the records on hand are accurate. Evidence and documentation of these checks must be kept and recorded.
- The **chief** executive, Queensland Health must be notified of any discrepancies (lost, stolen or misappropriated) in scheduled medicines obtained under the approval. Details on how to do this, including the standard [notification form](#), are available via the [Queensland Health website](#).
- Approved organisations must provide, at six (6) monthly intervals, details on the frequency of use of each of the scheduled medicines obtained under the approval. This information must be sent to the Healthcare Approvals and Regulation Unit, and can be

made using the medicines usage report template attached to the approval and published on the [Queensland Health website](#).

7. General information on approvals

7.1. Format conditions and validity

- Approvals may contain a number of conditions and compliance with these conditions is mandatory.
- Section 18(4) of the Regulation requires that where an approval is granted, and conditions are imposed on the approval, the applicant must be given a written notice that states:
 - the reasons for the condition; and
 - that the applicant may seek a review of the imposition of the conditions within 28 days after the applicant receives notice of the decision, to the Queensland Civil Administration Tribunal (QCAT).
- Approvals may be issued with an expiry date up to two (2) years after the approval was granted. However, approvals may be granted for any period less than two years, depending on the applicant's circumstances and an assessment made by a delegate of the chief executive.
- Queensland Health does not send out reminder notices relevant to the expiry of an approval. If an approval is required beyond the expiry date, a new application should be made approximately one month prior to expiry (to allow time for processing). There is no guarantee that any application will be granted, and each application must be considered in the same manner as an original application, and on its merit.

7.2. Lost, stolen or destroyed approvals

- Approval holders may apply for a replacement approval if it is lost, stolen or destroyed. The application for replacement should detail the grounds for the request and should be in the form of a signed letter addressed to the Chief Executive, Queensland Health. It may be sent via email to HARU@health.qld.gov.au or post to Healthcare Approvals and Regulation Unit (HARU), Queensland Health, Locked Bag 21, Fortitude Valley, Queensland, 4006.

7.3. Change of name or ownership

- Approvals are not transferable across different entities. Accordingly, approval holders must notify Queensland Health if the approved organisation changes name or ACN during the term of the approval because the approval may no longer be valid. If the change is due to a change in ownership of the organisation, a new application is required, otherwise an [amendment application](#) will be required.

7.4. Powers of inspectors

- Under the *Health Act 1937*, inspectors (usually Environmental Health Officers from Queensland Health) may enter and inspect a public place open to the public, or with the consent of the occupier, or to a place open for carrying on business or otherwise open for entry to account for scheduled medicines kept at the place by the holder of an approval.
- After entry into a location, inspectors may search, inspect, examine, photograph, take extracts from or remove for examination, any scheduled medicines or other things relevant to enforcing compliance with the Regulation, at the location. Inspectors may remove any scheduled medicines for analysis or seize the scheduled medicines or any articles which an inspector believes to be a scheduled medicine. Inspectors may also check, copy and take extracts from any record, book, prescription or other document relating to scheduled medicines held at the location.

8. Supporting documents

For further guidance please refer to:

- [Guideline – Procedures and protocols for medicines management](#)
- [Notification to the Chief Executive of scheduled medicine discrepancy, loss or theft](#)
- [Schedule 8 controlled drug destruction form](#)
- [Purchase order template for scheduled drugs and/or poisons](#)

Contact details

Applications – Healthcare Approvals and Regulation Unit (HARU)

Tel: 07 3708 5264

Email: HARU@health.qld.gov.au

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

Appendix 1: Medicines list

The table below lists the scheduled medicines that are typically authorised for administration or supply by a registered nurse under an *Approval to use scheduled medicines for treatment of acute health conditions at isolated locations* and the conditions that typically apply to dealing with the medicines.

TABLE 1: Administration and supply to a patient by a registered nurse in accordance with the approved organisation’s clinical practice protocols and subject to the conditions described in the table and any conditions imposed under an approval

Drug type	Administration	Supply
Schedule 2	A registered nurse may administer	A registered nurse may supply only on the oral or written instruction of the nominated doctor
Schedule 3	A registered nurse may administer	A registered nurse may supply only on the oral or written instruction of the nominated doctor
Schedule 4	A registered nurse may administer only on the oral or written instruction of the nominated doctor	Only the following drugs (and formulations) may be supplied by a registered nurse on the nominated doctor’s written or oral instruction: <ul style="list-style-type: none"> • Antibiotics/antifungals/antivirals – only oral formulations, eye/ear drops or ointments • Benzodiazepines – 3 day’s supply only; oral formulations only • Steroids – dermal and topical rectal only • Antiemetics/antispasmodics – oral formulations only
Schedule 8	A registered nurse may administer on the oral or written instruction of the nominated doctor	No supply is permitted