Queensland Health

Application form – General approval (acute health conditions at isolated sites) – Initial application

January 2022

Information about this application form

This application form is to be used to apply for a general approval for **acute health conditions at isolated sites** under section 75 of the *Medicines and Poisons Act 2019* (**MPA**).

An **isolated site** is defined in schedule 16 of the *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**) as a remote site for which limited medical and pharmaceutical services are available (for example, mine sites).

Persons who have previously held an approval under the *Health (Drugs and Poisons) Regulation 1996* (**HDPR**) for 'Treatment of acute health conditions at isolated locations', or an approval for a mine site or island resort, should use this form.

For persons seeking to provide emergency first aid, including paramedic services, please see the Application form – General approval (emergency first aid) – Initial application.

Mine sites

Mine sites **do not** require a general approval under the MPA to buy and administer S4 inhaled analgesics, such as nitrous oxide or methoxyflurane, as under schedule 13, part 6, division 2 of the MPMR, a mine manager (person in charge of a mine) may give a purchase order to buy stock of an S4 inhaled analgesic for first aid treatment of persons at the mine.

Under schedule 13, part 6, division 3 of the MPMR a first aid provider employed at a mine who has completed training from a registered training organisation about using an S4 inhaled analgesic, may possess and administer the medicine for the first aid treatment of a person at the mine. If the medicine is methoxyflurane, the first aid provider may administer one dose of no greater than 3 millilitres. Higher or subsequent doses must only be administered on the prescription of a medical practitioner or nurse practitioner.

Where a mine does not meet these conditions, or is seeking additional medicines, a general approval granted by Queensland Health under the MPA is required. Check with Healthcare Approvals and Regulation Unit (**HARU**) via HARU@health.qld.gov.au if you are unsure.

Scope of a general approval for acute health conditions at isolated sites

The holder of a substance authority, including a person acting under a substance authority, is authorised to carry out a regulated activity with a regulated substance in the authorised way (ss31 and 62 of the MPA). A *general approval* is a type of substance authority that may be granted under the MPA (ss61 and 68 of the MPA).

A general approval for acute health conditions at isolated sites authorises the holder (including persons stated in the approval to be acting for the approval holder) to carry out

the following regulated activities with the regulated substances (medicines) stated in the approval (schedule 16, part 1 of the MPMR):

1. A medical practitioner or nurse practitioner employed (includes contracted) by the approval holder to give a purchase order to buy stock of the medicines stated in the approval.
2. A senior person at an isolated site (being the person responsible for daily operations at the site – as defined in schedule 16, part 1 of the MPMR) employed by the approval holder, to possess the medicines at an isolated site stated in the approval.
3. A registered nurse employed by the holder of the approval to possess and give a treatment dose of an S2, S3 or S4 medicine stated in the approval, on a prescription from a medical practitioner or nurse practitioner (this is in addition to a registered nurse's authority to administer and dispose of medicines).

What this class of approval does not authorise

A general approval for acute health conditions at isolated sites **does not** authorise:

- the use of any 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 approval holder to provide treatment from a location where Schedule 2 medicines may be sold under an S2 retail licence.

Requirements and conditions

Authorised way – section 31 of the MPA

All substance authorities are subject to the requirements and standard conditions specified in the relevant regulation, in this case, the MPMR, that applies to that type of substance authority, and any additional or varied conditions specified on the substance authority. These conditions may limit or specify how the regulated activities must be carried out.

Any person carrying out a regulated activity with a regulated substance must do so in the authorised way and a person to whom a substance authority applies must comply with the conditions of the authority. Failure to comply with these requirements may result in regulatory action being taken, including prosecution, which may attract a significant penalty.

Requirements and standard conditions for general approvals for acute health conditions at isolated sites

Unless stated otherwise in the approval, the following requirements and standard conditions described in sections 70 and 91 of the MPA and prescribed in the following chapters of the MPMR, apply to general approvals for acute health conditions at isolated sites:

- chapter 3 of the MPMR 'Standard conditions for substance authorities' – part 5 'General approvals', division 1 'Acute health conditions at isolated sites' and part 6 'All substance authorities'

- chapter 4 of the MPMR 'General requirements for dealings' – part 3 'Buying by giving purchase orders', part 6 'Prescribing medicines', part 7 'Making standing orders', part 9 'Giving treatment doses of medicines', part 10 'Administering medicines' and part 11 'Disposing of waste from diversion-risk medicines' and
- chapter 8 of the MPMR 'Offences' – part 2 'Secure storage systems', part 4 'Recording and keeping information', and part 5 'Reporting particular matters'.

1. The approval holder must appoint a medical practitioner or nurse practitioner who is appropriately qualified to oversee the dealings authorised under the approval (s32 of the MPMR).
2. The approval holder must take all reasonable steps to ensure a medical practitioner or nurse practitioner is available to be contacted when a dealing is carried out under the approval (s33 of the MPMR).
3. For buying stock of a medicine, the general approval holder and persons acting under the approval must comply with the requirements stated in chapter 4, part 3 of the MPMR 'Buying by giving purchase orders'.
4. For prescribing a medicine, the approval holder and persons acting under the general approval must comply with the requirements stated in chapter 4, part 6 of the MPMR 'Prescribing medicines'.
5. For making standing orders, the approval holder and persons acting under the general approval must comply with the requirements stated in chapter 4, part 7 of the MPMR 'Making standing orders'.
6. For giving a treatment dose of a medicine, the approval holder and persons acting under the general approval must comply with the requirements stated in chapter 4, part 9 of the MPMR 'Giving treatment doses of medicines'.
7. For administering a medicine, the approval holder and persons acting under the general approval must comply with the requirements stated in chapter 4, part 10 of the MPMR 'Administering medicines'.
8. For disposing of waste from a diversion-risk medicine, the approval holder and persons acting under the general approval must comply with the requirements stated in chapter 4, part 11 of the MPMR 'Disposing of waste from diversion-risk medicines'.
9. The approval holder and persons acting under the general approval must securely store medicines in accordance with the requirements stated in chapter 8, part 2 of the MPMR 'Secure storage systems'.
10. The approval holder and persons acting under the general approval must establish and maintain a medicines register, to track all the regulated activities with medicines under the substance authority until medicines are completely used or destroyed, in accordance with chapter 8, part 2, division 3 of the MPMR 'Medicines registers'.
11. Where an approval holder, or a person acting under the general approval, reasonably suspects a diversion-risk medicine has been lost or stolen, the holder must give notice about the incident to the chief executive of Queensland Health (or delegate) in the approved form and notify the Queensland Police Service about the incident as soon as practicable, but no later than the end of the next business day after the incident (s226 of the MPMR).

12. The approval holder must ensure any records required to be kept under the MPA in relation to an authorised place stated in the authority are available for inspection from the place, and if the records are kept electronically, the approval holder must ensure the records for each authorised place stated in the substance authority are available for inspection from the primary place of business of the approval holder (s41 of the MPMR).
13. Where a record must be made or kept, approval holders must take all reasonable steps to ensure (s224 of the MPMR):
    a. the record is kept in a retrievable form, and is kept securely to ensure it cannot be altered, obscured, deleted or removed without detection; and
    b. the record is kept for a period of two years after it is made, or for a medicine register, for two years after the last entry in the register is made.
14. The approval holder must give notice to the chief executive of Queensland Health (or delegate) in the approved form if any of the following changes are proposed by the approval holder (s42 of the MPMR):
    a. a change to an authorised place stated in the substance authority;
    b. a change to a relevant person stated in the substance authority (such as a medical practitioner, nurse practitioner or senior person at an isolated site); and
    c. another change to the approval holder's circumstances that substantially affects the holder's ability to comply with a condition of the substance authority.
15. Where the approval holder proposes to stop carrying out a dealing with a medicine under a substance authority, the holder must give the chief executive of Queensland Health (or delegate) a notice in the approved form stating the following information (s43 of the MPMR):
    a. the day the dealing is proposed to stop;
    b. the amount of medicines that are likely to be unused on that day, if any; and
    c. how the approval holder proposes to deal with any unused medicines.

Information about general approvals for acute health conditions at isolated sites

Supervision

Because approvals require communication and co-ordination between the practitioners and the registered nurses, it is up to the appointed practitioners to determine which medicines are required, based on the isolated site's circumstances and the competencies of the registered nurses.

In compliance with section 32 of the MPMR, holders of general approvals for acute health conditions at isolated sites must appoint a medical practitioner or nurse practitioner to oversee the activities authorised under the approval.

Further, in compliance with section 33 of the MPMR, the holder of the general approval must take all reasonable steps to ensure that a medical practitioner or nurse practitioner is available to be contacted when a dealing is carried out under the approval, e.g. to provide prescriptions to registered nurses providing treatment under the general approval at any time nursing services are being provided.

Substance management plans – chapter 4, part 2 of the MPA

A substance management plan (**SMP**) is a document setting out how known and foreseeable risks associated with any regulated activity with a regulated substance are to be managed at a regulated place (s92 of the MPA). Applicants for general approvals for acute health conditions at isolated sites must have an SMP that meets the requirements specified in section 93 of the MPA and in the *Departmental standard: Substance management plans for medicines* under the MPMR, detailing what governance is in place to ensure that medicines will be managed effectively. A guideline for developing an SMP for medicines is available on the Queensland Health website.

To provide sufficient time for approval holders to comply with this new requirement, an SMP is not required until 1 year after the commencement of the MPA, i.e. 27 September 2022. Despite this, applicants should be able to demonstrate how they intend to manage and mitigate risks, by having in place appropriate procedures and protocols – as was required under the HDPR.

Duration of approvals

Section 69 of the MPA provides that the chief executive of Queensland Health (or delegate) determines the duration of a granted substance authority. General approvals for acute health conditions at isolated sites will usually be granted for two years, but a shorter term may be granted if requested or if the chief executive of Queensland Health (or delegate) determines that a shorter period is appropriate.

Change of name, location or circumstances

Substance authorities are not transferable across different entities. Accordingly, substance authority holders must notify Queensland Health if the authorised entity intends to change their name or ACN/ABN; change premises; or has another change in circumstances during the term of the substance authority, because this may mean that the authority is no longer valid. If the change is due to a change in ownership of the entity, or the chief executive of Queensland Health (or delegate) otherwise considers the change to be substantial, a new application will likely be required; in other circumstances, an amendment application may be required.

Applying for a general approval

In determining the application, the matters described in section 76 of the MPA may be taken into consideration.

Queensland Health assesses all information relevant to an application including:

- prior compliance history;
- background, skills and qualifications of persons who will be responsible for overseeing activities to be carried out or will have access to regulated substances;
- which regulated substances are to be included in the substance authority;
- proposed activities and locations where regulated substances are to be used and stored; and
- the documented governance arrangements in place relevant to the substance authority.

All applications are assessed individually, and there is no guarantee that a substance authority will be granted to any applicant.

Under chapter 3, part 3, division 4 of the MPA, applications are decided within 90 days of the application (final consideration day – section 86 of the MPA), or the latest day the chief executive of Queensland Health (or delegate) receives information from the applicant (section 89 of the MPA), unless a later date is agreed (s88 of the MPA). Applications not decided by this time are taken to have been refused (s89(4) of the MPA).

To apply, submit via email the **attached** application form, accompanied by all supporting documents (certified where required), to:

The Chief Executive, Queensland Health
c/o Healthcare Approvals and Regulation Unit (HARU)
medicines.applications@health.qld.gov.au

Queensland Government

Queensland Health

Medicines and Poisons Act 2019

MPA-75GIS
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APPLICATION FOR A GENERAL APPROVAL (ACUTE HEALTH CONDITIONS AT ISOLATED SITES)

Privacy statement – please read carefully

Personal information collected by Queensland Health is handled in accordance with the *Information Privacy Act 2009*. Queensland Health is collecting your personal information on this form under authority of the *Medicines and Poisons Act 2019*. The information is being collected to ensure that health risks arising from the use of regulated substances are appropriately managed. All personal information will be securely stored and only accessible by Queensland Health. Your personal information will not be disclosed to any other third parties without consent unless the disclosure is authorised or required by law. For information about how Queensland Health protects your personal information or to learn about your right to access your own personal information, please see our website at www.health.qld.gov.au/global/privacy.

Section 1 – Applicant (entity) details

Provide details of the legal entity (individual/organisation) seeking the approval

Type of entity seeking the approval		Specify type (if another entity)	

Name of entity (e.g. individual (surname, given names), partnership, company, incorporated association)

Trading name (if applicable)		ACN (if applicable)	
Entity phone		Entity email	

Postal address		Town/ Suburb		P/C	
Contact person		Phone		Email	

☐ Attach a current **company extract** from the Australian Securities and Investments Commission (ASIC) (if applicable)

Section 2 – Relevant persons (s76 and Schedule 1 MPA)

All applications must include completed Details of relevant person forms (MPA-76) for each of the following:

1. (a) If the approval is to be issued to a sole trader, the **applicant** must complete the relevant person form.
   (b) If the approval is to be issued to a partnership, **each partner** must complete the relevant person form.
   (c) If the approval is to be issued to a body corporate, an **executive officer** (executive director, company secretary, chief executive officer, general manager or chief financial officer) must complete the relevant person form.
2. A senior person (the person responsible for daily operations at the site e.g. site manager/supervisor) must be nominated for each premises on the approval. **Each senior person** must complete the relevant person form.
3. **Each medical practitioner** or **nurse practitioner**, nominated to be responsible for providing governance and oversight, prescriptions to registered nurses, and to purchase the medicines must complete the relevant person form.

☐ Attach completed details of relevant person forms for each person relevant to this application

Section 3 – Premises where medicines are to be stored and used

Provide details of the physical address where medicines are to be stored and used. To include additional sites on the same approval, please attach further details.

Isolated site 1

Site Name					
Site Address		Town /Suburb		P/C	
Contact person		Phone		Email	

Description of services to be provided at **this site**

Days/Times when services are to be provided

Storage location (e.g. building/room number)

Nature of storage (details of room, receptacle etc.)

Control of access (details of safe, keyholders etc.)

Isolated site 2

Site Name

Site Address | Town /Suburb | P/C

Contact person | Phone | Email

Description of services to be provided at **this site**

Days/Times when services are to be provided

Storage location (e.g. building/room number)

Nature of storage (details of room, receptacle etc.)

Control of access (details of safe, keyholders etc.)

Section 4 – Substance management plan (s93 MPA, Chapter 6 and Schedule 17 MPMR)

The holder of a general approval for acute health conditions at isolated sites, must make a substance management plan before any regulated activity happens with a regulated substance at, or in connection with, a regulated place (an isolated site), unless the person has a reasonable excuse.

The substance management plan must:

- state the following:
  - the day the plan starts;
  - the location of the place;
  - the regulated activities and regulated substances to which the plan applies;
  - the persons (staff) to whom the plan applies; and
- address the matters specified in the Departmental standard: 'Substance management plans for medicines' under the MPMR; and
- be written in a way that is likely to be easily understood by staff.

The approval holder (as 'responsible person') must ensure the substance management plan:

- is made available to staff when it is made; and
- is reviewed at the time specified in the MPMR.

NOTE: A SUBSTANCE MANAGEMENT PLAN IS NOT REQUIRED UNTIL 27 SEPTEMBER 2022 (s280 MPA)

Have you prepared a substance management plan that meets the criteria above and the Departmental standard: 'Substance management plans for medicines' of the MPMR?	☐ Yes	☐ No

Section 5 – Duration of the substance authority (s69 MPA)

General approvals for acute health conditions at isolated sites may be granted for up to two years, but a **shorter term** may be requested/granted.

Please specify the term of approval sought:

☐ 1 year	☐ 2 years	☐ Another term, please specify

Section 6 – Additional information and attachments

Provide any additional information to support your application

Provide/specify which attachments are attached to support this application:

☐ A current **company extract** from the Australian Securities and Investments Commission (ASIC)

☐ Details of **relevant person forms** for each person relevant to the application (directors, medical practitioners, nurse practitioners, senior persons e.g. site supervisors etc.)

☐ Other **relevant documents** (e.g. letter or contract confirming engagement of services, operational procedures) please specify

Section 7 – Consent and declaration

By making this application:

☐ I declare that I have authority to make this application on behalf of the applicant.

APPLICATION FOR A GENERAL APPROVAL (ACUTE HEALTH CONDITIONS AT ISOLATED SITES)

☐ I consent to Queensland Health making enquiries of, and exchanging information with, the authorities of any Australian state or territory, or of the Commonwealth, regarding any matters relevant to this application. If relevant information cannot be obtained from other entities, Queensland Health will determine the application on the information available.	
☐ I declare that, to the best of my knowledge, all information provided in and with this application form is true and correct in every detail.	
☐ I understand that if anything has been stated in this application form, or in an attachment provided with this application, that is false or misleading, any substance authority granted may be suspended or cancelled.	
Full name of applicant or authorised representative (where applicant is a body corporate or another entity)	Designation of applicant or authorised representative
Signature of applicant or authorised representative (where applicant is a body corporate or another entity)	Date (DD/MM/YYYY)