

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

January 2022

Information about this application form

This application form is to be used to apply to amend a general approval for **acute health conditions at isolated sites** under section 78 of the *Medicines and Poisons Act 2019 (MPA)*.

Applying for an amendment of a general approval for acute health conditions at isolated sites

The chief executive of Queensland Health (or delegate) must decide whether or not to grant an amendment application. In determining the application, the matters described in section 79 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.

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

**APPLICATION TO AMEND 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.

INSTRUCTIONS:

Sections 1 and 6 must be completed. In addition to this, please complete the relevant sections for which amendment is sought indicating whether the information is to be added, removed or updated.

Section 1 – Applicant details			
<i>Provide current details of the substance authority holder seeking the amendment</i>			
Substance authority reference			
Name of substance authority holder			
Entity phone	Entity email		
Section 2 – Changes to substance authority holder details			
<i>Provide updated details of the substance authority holder. Note that substance authorities are not transferrable.</i>			
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	
Section 3 – Changes to relevant persons (s76 MPA)			
<i>To add or update details for relevant persons e.g. partners, executive officers of a body corporate, senior person, nominated medical practitioner etc., indicate the changes below and attach a Details of relevant person form (MPA-76) for the person to be added/updated. To remove a relevant person, provide details below. If more space is required, please attach further details.</i>			
Partners/Executive officers (directors, CEO etc.) to add or update (attach relevant person form for each)			
Name	Add	Update	
Name	Add	Update	
Partners/Executive officers (directors, CEO etc.) to remove			
Name	Remove		
Name	Remove		
A person who is, or is proposed to be, responsible for overseeing or supervising regulated activities (senior person e.g. site manager/supervisor, medical practitioner or nurse practitioner) to add or update (attach relevant person form for each)			
Name	Add	Update	
Name	Add	Update	

**APPLICATION TO AMEND A GENERAL APPROVAL
(ACUTE HEALTH CONDITIONS AT ISOLATED SITES)**

A person who is, or is proposed to be, responsible for overseeing or supervising regulated activities (senior person e.g. site manager/supervisor, medical practitioner or nurse practitioner) to remove

Name	Remove
Name	Remove

Section 4 – Changes to premises where substances are to be stored and used

Provide details of changes to the physical address where substances are to be stored and used. If adding or updating site details, complete all fields. If removing, provide site name, address and end date. If more space is required, please attach further details.

Isolated site 1

Add	Remove	Update
Site Name		
Street Address		Town /Suburb P/C
Contact person	Phone	Email
Description of services to be provided at this location, including days/times		
Storage location (e.g. building/room number)		
Nature of storage (details of room, receptacle etc.)		
Control of access (details of safe, keyholders etc.)		
Does the storage at this location meet the requirements of s198 of the MPMR?		Yes No

Isolated site 2

Add	Remove	Update
Site Name		
Street Address		Town /Suburb P/C
Contact person	Phone	Email

**APPLICATION TO AMEND A GENERAL APPROVAL
(ACUTE HEALTH CONDITIONS AT ISOLATED SITES)**

Description of services to be provided at this location, including days/times		
Storage location (e.g. building/room number)		
Nature of storage (details of room, receptacle etc.)		
Control of access (details of safe, keyholders etc.)		
Does the storage at this location meet the requirements of s198 of the MPMR?	Yes	No

Section 5 – Additional information and attachments

Provide any additional information to support your application

Provide/specify which (if any) 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. operational procedures, clinical practice protocols) please specify

Section 6 – Consent and declaration

By making this application:

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

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.



**APPLICATION TO AMEND A GENERAL APPROVAL
(ACUTE HEALTH CONDITIONS AT ISOLATED SITES)**

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)