Application form – General approval (therapeutic) – Renewal application

September 2021

Information about this application form

This application form is to be used to apply to renew a general approval for **therapeutic use of medicines and/or prohibited substances** under section 82 of the *Medicines and Poisons Act 2019* (**MPA**). This is a non-specific form, to be used to apply to renew a general approval where there is no prescribed class in the *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**). Where there are prescribed classes i.e. emergency management of animals, emergency first aid, acute health conditions at isolated sites, applicants must use the specific application form.

For persons seeking to renew an approval to use medicines, poisons or prohibited substances for non-therapeutic use, including to conduct research, please see the Application to renew a general approval (non-therapeutic) under section 82 of the Medicines and Poisons Act 2019.

Applying for a renewal of a general approval

Timing

A renewal application must be made using the attached application form within the period starting 90 days before the term of the substance authority ends (s82(2) of the MPA). In exceptional circumstances, a late application may be accepted up to 30 days after the term of the current authority ends (s82(3) of the MPA).

If an application to renew a substance authority is accepted, the authority continues in force until the application is decided or taken to have been withdrawn (s85 the MPA).

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).

Assessment

The chief executive of Queensland Health (or delegate) must decide whether or not to grant a renewal application. In determining the application, the matters described in section 83 of the MPA may be taken into consideration, including any changes to matters that were considered by the chief executive of Queensland Health (or delegate) when the substance authority was granted.

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.

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-82GME
Version 1:09/2021
APPLICATION TO RENEW A GENERAL APPROVAL – THERAPEUTIC

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. Failure to provide information may render the form incomplete, which may constitute an offence under the *Medicines and Poisons Act 2019*. 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 details

*Provide **current** details of the substance authority to be renewed (to update details, submit an amendment application)*

Substance authority reference	
Name of substance authority holder	
Phone	Email

Section 2 – Changes to matters (s83 MPA)

Provide details of any changes to matters considered by the chief executive of Queensland Health (or delegate) when the substance authority was granted – this is for consideration of this application. In addition to describing any changes for the purpose of this renewal, please note that you are required under s42 of the Medicines and Poisons (Medicines) Regulation 2021 (MPMR) to give a notice to the chief executive of Queensland Health (or delegate) of the changes in the approved form titled Notification of particular changes affecting authority (MPMR-42). Should you wish to amend your approval, submit an amendment application (MPA-78GME)

Changes to premises e.g. storage, security

Changes to personnel e.g. management, supervisors and key staff

Changes to substances being used

Changes to operations

Section 3 – Substance management plan (s93 MPA, Chapter 6 and Schedule 17 MPMR)

The holder of a general approval may be required to make a substance management plan before any regulated activity happens with a regulated substance at, or in connection with, a regulated place (e.g. a location stated in the approval), unless the person has a reasonable excuse. In some instances, applicants may be required to operate under another entity's SMP e.g. where a general approval is granted to a person to carry out a regulated activity at a hospital, the hospital's SMP may apply.

If a substance management plan is required, it 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 must ensure any substance management plan prepared:

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

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
OR		
Will you be working for an entity (e.g. Hospital and Health Service) that has a substance management plan for the place where the regulated substances will be used that meets (and continues to meet) the criteria above and the Departmental standard: 'Substance management plans for medicines'?	☐ Yes	☐ No

Section 4 – Duration of the substance authority

Please specify the desired term or end date for the renewal of the general approval, providing justification. Applicants should note that typically general approvals will not be issued for more than two years.

Please specify the term of approval sought:

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

Section 5 – Additional information and attachments

Provide any additional (new/updated) information to support your application, including additional qualifications or training such as anaphylaxis training or training in the quality use of medicines, credentialing from the hospital, details of project grant and/or proposal, ethics committee approval etc).

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

☐ For entities, 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, senior persons e.g. managers/supervisors etc., persons intended to possess or use regulated substances)

☐ Certified copies of additional **qualifications or training**

☐ Evidence of the **credentialing process** used to prove that persons providing treatment have the necessary competence and training to use regulated substances

☐ Other **documents** (e.g. operational procedures, treatment protocols, ethics approval etc.) please specify

APPLICATION TO RENEW A GENERAL APPROVAL – THERAPEUTIC

Section 6 – Employer endorsement (individual applicants only)

This section is only required to be completed for applications made by individuals.
This section should be completed by the applicant's supervisor or employer. For applicants employed by a Hospital and Health Services (HHS), this section must be signed by the Chief Executive of the HHS.

Employing entity					
Street Address		Town /Suburb		P/C	
Full name of endorser					
Position		Phone		Email	

Declaration

I confirm that the information provided by the applicant,	Applicant Name

is true and correct, and that there is still a **genuine need** for the applicant to possess and use the regulated substances listed on this application as part of their employment. I support this application to **renew the general approval for the proposed term**.

Signature		Date	

Section 7 – 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.

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)

Clear form