Queensland Health

Application form – General approval (therapeutic) – Amendment application

June 2022

Information about this application form

This application form is to be used to apply to amend a general approval for **therapeutic use of medicines and/or prohibited substances** under section 78 of the *Medicines and Poisons Act 2019* (**MPA**). This is a non-specific form, to be used to apply to amend a general approval where there is no specific class in the *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**). Where there is a specific classes i.e. emergency management of animals, emergency first aid, acute health conditions at isolated sites, or immunisation program, applicants must use the specific application form. Similarly, to apply to amend a prescribing approval, applicants must amend the prescribing approval using the correct form.

For persons seeking to amend an approval to use medicines, poisons or prohibited substances for **non-therapeutic use**, including to conduct research, please see the relevant poisons general approval application form.

Applying for an amendment of a general approval

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

Queensland Government

Queensland Health

Medicines and Poisons Act 2019

MPA-78GME
Version 2:06/2022

APPLICATION TO AMEND 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. 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 10 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 (entity) details

*Provide **current** details of the substance authority holder seeking the amendment*

Substance authority reference	
Name of substance authority holder	
Entity phone	Entity email

Section 2 – Changes to substance authority holder details

*Provide **updated** details of the substance authority holder. Note that substance authorities are not transferrable.*

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

Trading name (if applicable)		ACN or ACNC (if applicable)	
Entity phone		Entity email	
Postal address		Town/ Suburb	P/C

Section 3 – Changes to relevant persons (s76 MPA)

To add or update details for relevant persons e.g. individual approval holders, partners, executive officers of body corporates, senior persons, persons possessing or using medicines or prohibited substances 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.

Individual applicant to update (attach relevant person form)

Name		☐ Update

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 veterinary surgeon) to add or update (attach relevant person form for each)

Name		☐ Add	☐ Update
Name		☐ Add	☐ Update

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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 veterinary surgeon) to remove		
Name		☐ Remove
Name		☐ Remove

Section 4 – Changes to regulated activities to be undertaken under this approval

*If changes are required to the regulated activities authorised under the general approval, specify **all** the regulated activities proposed to be undertaken under the amended approval. Note: do not include activities not required e.g. health professionals at hospitals do not need authority to buy medicines.*

☐ Buy	☐ Give a treatment dose	☐ Administer
☐ Possess	☐ Dispense	☐ Dispose (of waste)
☐ Prescribe (veterinary surgeons only)		

Section 5 – Changes to regulated substances proposed to be used under this approval

Provide details of changes to the regulated substances intended to be used under the approval, including name, form strength, pack size/volume, with reference to the schedule and name used in the latest Poisons Standard. Provide justification for each substance to be added/updated, outlining the need for access to each substance, including the circumstances in which it will be used.

A. Substances to be added

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Volume/Use
-				
-				
-				
-				
-				

Justification

B. Substances to be removed

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Volume/Use
-				
-				
-				
-				
-				

C. Substances to be updated

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Volume/Use
-				
-				
-				
-				
-				

Justification

Section 6 – Changes to supervision and/or prescription

Provide details of the changes to the supervision or prescription requirements, for example changes to the type of supervision/prescription, changes to who is proposed to provide the supervision/prescription and their position or who is no longer to provide supervision/prescription and changes to which regulated substances or regulated activities the supervision/ prescription applies to or no longer applies to.

Changes to supervision or prescription details

Section 7 – Changes to locations where regulated substances are to be stored and used

Provide details of changes to locations where regulated substances are to be used and stored. To include additional locations, attach further details.

Location 1

☐ Add ☐ Remove ☐ Update

Ward or Building (if relevant)

Premises Name

☐ Health service/facility
☐ Commercial/industrial

Street Address | Town/ Suburb | P/C

Contact person | Phone | Email

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 ss197-199 of the MPMR?	☐ Yes	☐ No

Location 2

☐ Add	☐ Remove	☐ Update

Ward or Building (if relevant)

Premises Name | ☐ Health service/facility ☐ Commercial/industrial

Street Address | Town/ Suburb | P/C

Contact person | Phone | Email

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 ss197-199 of the MPMR?	☐ Yes	☐ No

Section 8 – 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 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 AMEND A GENERAL APPROVAL (THERAPEUTIC)

Section 9 – Employer endorsement (individual applicants only)

This section is only required to be completed for amendment 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 by employer

I confirm that the information provided by the applicant,

is true and correct, and that there is a **genuine need** for the applicant to possess and use the regulated substances under their approval (as amended by this application) as part of their employment. I support this application to **amend** the applicant's approval in the way requested.

Signature		Date	

Section 10 – 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 consent to Queensland Health collecting, using and disclosing information submitted with this application including to, for example, the Medicines Expert Advisory Group (or similar) for the purpose of determining this application and any matters relevant to the related substance authority.
- ☐ 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 (position) 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