Queensland Health

Application form – General approval (therapeutic) – Initial application

June 2022

Information about this application form

Therapeutic use

This application form is to be used to apply for a general approval for the **therapeutic use of medicines and/or prohibited substances** under section 75 of the *Medicines and Poisons Act 2019* (**MPA**). As per part 1 of the Poisons Standard, "Therapeutic use" means use in or in connection with:

a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in human beings or animals;

b) influencing, inhibiting or modifying a physiological process in human beings or animals;

c) testing the susceptibility of human beings or animals to a disease or ailment;

d) influencing, controlling or preventing conception in human beings or animals;

e) testing for pregnancy in human beings or animals; or

f) the replacement or modification of parts of the anatomy in human beings or animals.

Correct form

All applications for substance authorities must be made on the relevant *approved form*. This is a non-specific form, to be used to apply for a general approval where there is no specified class under the *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**). Where there is a specific class of general approval 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 for approval to prescribe medicines for human therapeutic use, applicants must apply for a prescribing approval. Veterinary surgeons may use this form for approval to prescribe restricted medicines.

Persons who have previously held an approval under the *Health (Drugs and Poisons) Regulation 1996* (**HDPR**) for 'Scheduled medicines and/or poisons for therapeutic use' should use this form. For persons seeking to use medicines, poisons or prohibited substances for non-therapeutic use, including to conduct research, please see the relevant poisons general approval application form.

Scope of a general approval

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).

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 therapeutic use of medicines and/or prohibited substances

Unless stated otherwise in the approval, the following requirements and standard conditions described in sections 70 and 91 of the MPA and specified in the following chapters of the MPMR, apply to general approvals:

- chapter 3 of the MPMR 'Standard conditions for substance authorities' – part 6 'All substance authorities'
- chapter 4 of the MPMR 'General requirements for dealings' – part 3 'Buying by giving purchase orders', part 5 'Possessing stock for delivery', part 6 'Prescribing medicines', part 7 'Making standing orders', part 8 'Dispensing medicines', 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. 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'.
2. 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'.
3. 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'.
4. For dispensing a medicine, the approval holder and persons acting under the general approval must comply with the requirements stated in chapter 4, part 8 of the MPMR 'Dispensing medicines'.
5. For giving treatment doses 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'.

6. 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'.
7. 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'.
8. 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'.
9. 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'.
10. 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).
11. 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).
12. 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.
13. 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 responsible for daily operations at a 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.
14. 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.

Prohibited substances for therapeutic use

Where an application is made for a general approval to authorise the carrying out of a regulated activity with a prohibited substance for a therapeutic purpose (e.g. to use etorphine to immobilise elephants), applicants can expect that relevant S8 medicine requirements under the MPMR, including those for diversion-risk medicines, will likely apply as conditions in relation to the general approval, to the extent the context permits. This means that:

- requirements in chapters 4 and 5 of the MPMR for dealing with S8s will apply (as per 1-7 under the heading 'Requirements and standard conditions for general approvals for therapeutic use of medicines and/or prohibited substances' above);
- requirements in chapter 8 of the MPMR for storage of S8 medicines will apply (as per 8 under the heading 'Requirements and standard conditions for general approvals for therapeutic use of medicines and/or prohibited substances' above);
- requirements in chapter 8 of the MPMR for keeping registers and records for S8s will apply (as per 9 and 12 under the heading 'Requirements and standard conditions for general approvals for therapeutic use of medicines and/or prohibited substances' above);
- requirements in Chapter 8 of the MPMR for reporting particular matters about S8s to the chief executive will apply (as per 10 under the heading 'Requirements and standard conditions for general approvals for therapeutic use of medicines and/or prohibited substances' above).

In addition, the standard conditions that apply to all substance authorities under the MPMR will apply (as per 11, 13 and 14 under the heading 'Requirements and standard conditions for general approvals for therapeutic use of medicines and/or prohibited substances' above). Applicants can expect that a substance management plan will likely need to be prepared for any place where regulated activities will be carried out with prohibited substances.

Information about general approvals

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 (section 92 of the MPA). Holders of general approvals (therapeutic) may be required, as a condition on the approval, to 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 (s280 MPA). 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. Please note however, that **Queensland Health does not approve SMPs** – read more about SMPs for medicines here.

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 therapeutic use 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.

An inspection of the premises may also be undertaken.

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-75GME
Version 2:06/2022
APPLICATION FOR 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.

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 MPA)

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

A. If the applicant is an individual, the **applicant** must complete the relevant person form.

B. If the approval is for an entity:

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** (directors, company secretary, chief executive officer/general manager and chief financial officer) must complete the relevant person form.
2. Where necessary, a **senior person** (e.g. manager/supervisor) that is responsible for managing day-to-day operations should be nominated and complete the relevant person form.
3. Each **person that intends to possess and/or use diversion-risk medicines or prohibited substances** under the approval, including any volunteers, must complete the relevant person form.

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

Section 3 – Purpose of approval

Provide a brief description of the intended purpose of the general approval, including justification for why a general approval is needed and how this 'need' is not currently being met. Attach evidence to support any claims.

Section 4 – Regulated activities proposed to be undertaken under this approval

Specify the regulated activities proposed to be undertaken under the 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 – Regulated substance/s proposed to be used under this approval

Please specify 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 required, outlining the need for access to each substance, including the circumstances in which it will be used.

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

Justification

Section 6 – Supervision and/or prescription

If it is intended that regulated substances are only to be dealt with under supervision (either direct supervision or (indirect) supervision) and/or on prescription (written and/or oral), please provide relevant details including the type of supervision/prescription, who is providing the supervision/prescription and their position, and which regulated substances or regulated activities the supervision/ prescription applies to.

Supervision details (if any)

Prescription details (if any)

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

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

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 – 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 (as 'responsible person') 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.

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
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 the criteria above and the Departmental standard: 'Substance management plans for medicines'?	☐ Yes	☐ No

Section 9 – Duration of the substance authority (s69 MPA)

Please specify the desired term or end date for 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

Justification for requested duration

Section 10 – Additional information and attachments

Provide any additional 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

Section 11 – 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 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 listed on this application as part of their employment. I support this application.

Signature	Date

Section 12 – 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