Queensland Health

Application form – Prescribing approval (therapeutic) – Initial application

September 2021

Information about this application form

This application form is to be used to apply for a **prescribing approval** under section 75 of the *Medicines and Poisons Act 2019* (**MPA**). This is a specific form, to be used by a prescriber (an individual) to apply for a prescribing approval, other than for approved opioids. For prescribing approved opioids under an opioid treatment program, applicants should use **this form**. For non-prescribers, for entities or to apply for authorisation to carry out a regulated activity other than prescribing, applicants should use the Application form – General approval (therapeutic) – Initial application.

Persons who have previously held an approval for regulated controlled drugs or regulated restricted drugs under the *Health (Drugs and Poisons) Regulation 1996* (HDPR) for 'Scheduled medicines and/or poisons for therapeutic use' should use this form.

Scope of a prescribing 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. A *prescribing approval* is a type of substance authority that may be granted under the MPA, that authorises a person to carry out the regulated activities stated in the approval, with the medicines stated and in the stated circumstances.

Prescribing approvals may only be granted to persons who are already authorised to prescribe medicines under the *Medicines and Poisons (Medicines) Regulation 2021* (**MPMR**) i.e. dentists, medical practitioners, physician assistants, nurse practitioners, endorsed midwives, endorsed optometrists, endorsed podiatrists, podiatric surgeons and veterinary surgeons.

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 prescribing approvals

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 prescribing 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 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 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 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 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 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 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 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 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 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 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 supervising medical practitioner); 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.

Common additional conditions

Under section 70 of the MPA, a substance authority is subject to a condition (a standard condition) prescribed by regulation to apply in relation to the substance authority and any additional or changed condition decided by the chief executive of Queensland Health (or delegate).

A commonly imposed additional condition for a prescribing approval is that prescribing of a restricted medicine stated in the prescribing approval must be under the supervision of the specialist stated in the approval.

Entities granted an approval should review their approval instrument carefully to ensure that any changed or additional conditions are met.

Information about prescribing approvals

Supervision

Applicants seeking to prescribe restricted medicines must enter into supervisory arrangements with a medical practitioner who holds the relevant specialisation. Restricted

medicines, which are listed in schedule 2, part 1 of the MPMR, and the relevant specialisations (as per schedule 6, part 2 of the MPMR) are as follows:

Restricted medicine	Specialisation
Acitretin	Dermatology, general medicine*
Ambrisentan	Cardiology, rheumatology, general medicine*
Amfetamines	Paediatrics, psychiatry
Bexarotene	Dermatology, haematology, medical oncology, general medicine*
Bosentan	Cardiology, rheumatology, general medicine*
Clomifene	Endocrinology, gynaecology or obstetrics
Clozapine	Psychiatry
Corifollitropin alfa	Endocrinology, gynaecology or obstetrics
Cyclofenil	Endocrinology, gynaecology or obstetrics
Dinoprost	Endocrinology, gynaecology or obstetrics
Dinoprostone	Endocrinology, gynaecology or obstetrics
Enzalutamide	Medical oncology, urology, general medicine*
Etretinate	Dermatology, general medicine*
Follitropin alpha	Endocrinology, gynaecology or obstetrics
Follitropin beta	Endocrinology, gynaecology or obstetrics
Isotretinoin for human oral use	Dermatology, general medicine*
Lenalidomide	Haematology, medical oncology, general medicine*
Luteinising hormone	Endocrinology, gynaecology or obstetrics
Macitentan	Cardiology, rheumatology, general medicine*
Methylphenidate	Paediatrics, psychiatry
Pomalidomide	Haematology, medical oncology, general medicine*
Riociguat	Cardiology, rheumatology, general medicine*
Sodium oxybate	Neurology, paediatrics, respiratory medicine or sleep medicine
Teriparatide	Endocrinology, geriatrics, rheumatology, general medicine*

Thalidomide	Dermatology, haematology, infectious diseases, medical oncology, general medicine*
Tretinoin for human oral use	Dermatology, general medicine*
Urofollitropin (human follicle stimulating hormone)	Endocrinology, gynaecology or obstetrics

**A specialisation in general medicine means a medical practitioner registered under the Health Practitioner Regulation National Law who has a specialist registration in general medicine (not to be confused with a general practitioner)*

Applicants seeking to prescribe other medicines may also need to enter into supervisory arrangements, depending on the circumstances.

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 prescribing approvals 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 (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.

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. Prescribing approvals 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 prescribing 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-75PRM
Version 1:09/2021
APPLICATION FOR A PRESCRIBING 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 details of the individual seeking the approval

Title		Surname		Given names	
Previous names (including maiden names)					
Health Profession				AHPRA Registration No.	
Work phone		Work email			

Do you have any conditions on your registration that would prevent you from prescribing, buying, possessing, dispensing, giving a treatment dose or administering the medicines you are applying for?	☐ Yes	☐ No

If yes, provide further details of the conditions on your registration

Section 2 – Location

Name of practice/clinic/hospital etc. where treatment will be provided

Street Address		Town /Suburb		P/C	
Postal Address		Town /Suburb		P/C	

Section 3 – Purpose of approval

Provide a brief description of the intended purpose of the prescribing approval, including justification for why a prescribing 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.

☐ Prescribe

☐ Buy ☐ Possess	☐ Give a treatment dose ☐ Dispense	☐ Administer ☐ Dispose (of waste)

Section 5 – Regulated substances proposed to be used under this approval

*Please specify the regulated substances intended to be used under the approval. Provide **justification for each substance** required, outlining the need for access to each substance, including the circumstances in which it will be used. For substances other than restricted medicines, include the name, form strength, pack size/volume, with reference to the schedule and name used in the latest Poisons Standard. Attach further information if required.*

☐ Acitretin	☐ Ambrisentan	☐ Amfetamines
☐ Bexarotene	☐ Bosentan	☐ Clomifene
☐ Clozapine	☐ Corifollitropin alfa	☐ Cyclofenil
☐ Dinoprost	☐ Dinoprostone	☐ Enzalutamide
☐ Etretinate	☐ Follitropin alpha	☐ Follitropin beta
☐ Isotretinoin for human oral use	☐ Lenalidomide	☐ Luteinising hormone
☐ Macitentan	☐ Methylphenidate	☐ Pomalidomide
☐ Riociguat	☐ Sodium oxybate	☐ Teriparatide
☐ Thalidomide	☐ Tretinoin	☐ Urofollitropin

☐ Another substance specifically prepared to stimulate ovulation

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

Justification

Section 6 – Supervision

If it is intended that regulated substances are only to be dealt with under supervision (either direct supervision or (indirect) supervision), please provide relevant details including the type of supervision, who is providing the supervision and their specialisation, and which regulated substances or regulated activities the supervision applies to.
*Applications to prescribe restricted medicines **must** include a supervisor with the relevant specialisation.*

Title	Surname	Given names
Specialisation		AHPRA Registration No.
Work phone	Work email	

Name of location where specialist practices					
Street Address		Town /Suburb		P/C	
Supervision details					

☐ I have agreement from the abovenamed supervisor to provide, under their supervision, treatment for patients with the medicines requested in section 5.

Clozapine

*Additional information is required for prescribing clozapine in the community. Provide details of the **clozapine coordinator** participating in the shared care arrangement. Contact your nearest mental health service for further information.*

Title		Surname		Given names	
Name of location where coordinator practices					
Work phone		Work email			

Monitoring service:

☐ Clopine connect ☐ CPMS (Clozapine patient monitoring system)

☐ I have received training from this clozapine coordinator

☐ I have entered into shared care arrangements with the coordinator to provide community-based treatment for patients with clozapine, under the supervision of the psychiatrist named above (in Section 6).

Section 7 – Substance management plan (s93 MPA, Chapter 6 and Schedule 17 MPMR)

The holder of a prescribing 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 prescribing 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 (if relevant); 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 8 – Duration of the substance authority (s69 MPA)

Please specify the desired term or end date for the prescribing approval, providing justification. Applicants should note that typically prescribing 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 9 – Additional information and attachments

Provide any additional information to support your application, including additional qualifications or training, 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:

☐ Certified photographic **proof of identity** for the applicant

☐ Certified copy of your **registration certificate** and any additional information (notices) regarding conditions of your registration

☐ 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 prescribe the relevant scheduled medicines

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

Section 10 – Disclosure

1. Have you been convicted of, or are there charges pending for, an indictable offence?	☐ Yes	☐ No

2. In relation to the following relevant legislation:
   - *Medicines and Poisons Act 2019*
   - *Health Act 1937* (including the Health (Drugs and Poisons) Regulation 1996) (repealed)
   - *Pest Management Act 2001* (repealed)
   - equivalent legislation in another Australian jurisdiction, including the *Therapeutic Goods Act 1989* (Cwth), *Narcotic Drugs Act 1967* (Cwth) and *Agricultural and Veterinary Chemicals Code Act 1994* (Cwth)

   have you (or a company of which you were a corporate officer):

a) been convicted of, or are there charges pending for, an offence?	☐ Yes	☐ No

b) held a licence, permit, approval, authority and/or an endorsement that was suspended or cancelled?	☐ Yes	☐ No
c) been refused a licence, permit, approval, authority and/or an endorsement?	☐ Yes	☐ No

Provide further details to questions answered 'yes'. Clearly indicate for each occurrence when the incident occurred and the circumstances.

Section 11 – 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