Queensland Health

Application form – Prescribing approval (restricted medicine) – Amendment application

September 2021

Information about this application form

This application form is to be used to apply to amend a **prescribing approval for a restricted medicine** under section 78 of the *Medicines and Poisons Act 2019* (**MPA**). To amend a prescribing approval for approved opioids for the Queensland Opioid Treatment Program (QOTP), please complete an application for a prescribing approval (QOTP) [link to QOTP page].

Applying for an amendment of a prescribing approval for a restricted medicine

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-78PRM
Version 1:09/2021

APPLICATION TO AMEND A PRESCRIBING APPROVAL (RESTRICTED MEDICINE)

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.

INSTRUCTIONS:

Sections 1 and 7 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

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

Substance authority reference	
Name of substance authority holder	
Phone	Email

Section 2 – Changes to substance authority holder details or location

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

Name					
Phone		Email			
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 – Changes to activities to be carried out

*Specify the **updated** regulated activities proposed to be undertaken under the approval. Provide justification for the amendment.*

☐ Prescribe

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

Provide justification to support your proposed change in regulated activities

APPLICATION TO AMEND A PRESCRIBING APPROVAL (RESTRICTED MEDICINE)

Section 4 – Changes to substances proposed to be prescribed under this approval

*Provide details of changes to the substances to be prescribed 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.*

A. Substances to be added

☐ 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

Alternatively, please list specific products to be added:

Schedule	Poisons Standard descriptor	Form	Strength	Pack size//Use

Justification

B. Substances to be removed

☐ 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		

Alternatively, please list specific products to be removed:

Schedule	Poisons Standard descriptor	Form	Strength	Pack size//Use

Justification

C. Substances to be updated

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Use

Change (for the substance above)

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Use

Change (for the substance above)

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Use

Change (for the substance above)

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Use

Change (for the substance above)

APPLICATION TO AMEND A PRESCRIBING APPROVAL (RESTRICTED MEDICINE)

Section 5 – Supervision

If it is intended that regulated substances are only to be dealt with under supervision (either supervision or direct 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.
*Amendment applications to add/update a restricted medicine **must** include a supervisor with the relevant specialisation – see the guideline with the initial application form. If amending supervisor details, please provide updated details below.*

Title		Surname		Given name/s	
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 authorised under this approval.

Clozapine

*Additional information is required for prescribing clozapine in the community. If adding clozapine or changing brand, provide details of the **clozapine coordinator** participating in the shared care arrangement. Contact your nearest mental health service for further information. If changing clozapine coordinator, provide updated details below.*

Title		Surname		Given name/s	
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 in my approval or the new psychiatrist named above (in Section 5).

Section 6 – Additional information and attachments

Provide any additional information (new/updated) to support your application, including additional qualifications or training, credentialing from the Hospital, details of project grant and/or proposal, ethics committee approval etc.

APPLICATION TO AMEND A PRESCRIBING APPROVAL (RESTRICTED MEDICINE)

Provide/specify which (if any) 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
- ☐ 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 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