Application for a prescribing approval for (Schedule 8) psychostimulants - Medicines and Poisons Act 2019

MPA-75,78,&82:PAMM Version 1:09/21

Information about this application form

This application form is to be used to apply for a **prescribing approval** under the *Medicines and Poisons Act 2019* (**MPA**).

'Prescribing approvals' are defined in section 67 of the MPA as follows:

A **prescribing approval** is an approval that authorises a person to carry out any of the following regulated activities with a medicine stated in the approval—

(a) prescribing the medicine for a person, or a class of persons, stated in the approval in the stated circumstances;
(b) buying, possessing, administering, dispensing and giving a treatment dose of the medicine in the stated circumstances.

This form is to be used to apply for:

- an initial application for a prescribing approval (section 75 of the MPA);
- an amendment of a prescribing approval (section 78 of the MPA); or
- a renewal of a prescribing approval (section 82 of the MPA)

for the treatment of a person with Schedule 8 psychostimulant medicines.

Your application WILL NOT be considered, or may be returned to you for completion, unless:

1. ALL parts of this application form are completed accurately;
2. ALL the relevant attachments are included; and
3. the Declaration is signed.

Scope of a prescribing approval

Prescribing approvals to treat a particular patient with Schedule 8 psychostimulants are limited to registered medical pracititioners.

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 (section 31 of the MPA). 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.

Requirements and conditions

Requirements and standard conditions for prescribing approvals

Unless stated otherwise in the approval, the requirements and standard conditions described in sections 70 and 91 of the MPA and prescribed in the following chapters of the Medicines and Poisons (Medicines) Regulation 2021, apply to the prescribing approval:

- chapter 3 ‘Standard conditions for substance authorities’, part 4 ‘Prescribing approvals for approved opioids’;
- chapter 4 ‘General requirements for dealings’, part 6 ‘Prescribing medicines’; and
- chapter 8 ‘Offences’..

The approval holder must notify the chief executive of Queensland Health (chief executive) or delegate in the approved form, as soon as practicable but no later than 5 business days, if the approval holder’s circumstances change in a way that substantially affects (section 42 of the Medicines and Poisons (Medicines) Regulation 2021):

a. a dealing the approval holder is authorised to carry out under the approval; or
b. the ability of the approval holder to comply with the conditions of the approval.

Applying for an initial prescribing approval

In determining the application for a prescribing approval, the matters in section 76 of the MPA may be taken into consideration.

Queensland Health assesses all information provided with an application including:

- background, skills and qualifications of persons who will be responsible for overseeing activities to be carried out or will have access to medicines;
- which regulated substances are to be included in the substance authority;

Applying for amendment of a prescribing approval

In determining the application for amendment, the factors in section 79 of the MPA may be taken into consideration.

Queensland Health assesses all information provided with an application to amend a prescribing approval including:

- the conditions of the substance authority; and
- any changes to the matters considered by the chief executive (or delegate) when the substance authority was granted.;

Applying for renewal of a prescribing approval

In determining the application for renewal, the factors in section 82 of the MPA may be taken into consideration.

Queensland Health assesses all information provided with an application to renew a prescribing approval including:

- the conditions of the substance authority; and
- any changes to the matters considered by the chief executive (or delegate) when the substance authority was granted;

If the chief executive (or delegate) decides to grant the renewal of the prescribing approval, the chief executive (or delegate) may also decide to take either of the following actions if they aresatisfied the action is reasonably necessary:

- impose additional conditions on the substance authority (section 70(1)(b) of the MPA);
- change a condition of the substance authority, including a standard condition (section 70(2) of the MPA).

All applications are assessed individually, and there is no guarantee that a prescribing approval, or an amendment or renewal of a prescribing approval will be granted to any applicant.

Under chapter 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 (or delegate) receives information from the applicant (section 89 of the MPA), unless a later date is agreed (section 88 of the MPA). Applications not decided by this time are taken to have been refused (section 89(4) of the MPA).

To apply, submit via email the **attached** application form, accompanied by all supporting documents 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-75,78,&82:PAMM
Version 1- 09/2021

Initial application, amendment or renewal for a prescribing approval for (Schedule 8) psychostimulants under the *Medicines and Poisons Act 2019*

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.

Application type

Initial application for prescribing approval to treat a patient with Schedule 8 psychostimulant medicine	☐
Application to **amend** an approval to treat a patient with Schedule 8 psychostimulant medicine Approval number	☐
Application to **renew** an approval to treat a patient with Schedule 8 psychostimulant medicine Approval number	☐

Section 1 – Applicant details (s76 MPA)

Provide details of the medical practitioner seeking the prescribing approval

Title	Surname	
Given name/s		
Medical Specialty	AHPRA Registration No	
Street Address		
Town /Suburb	State	P/C
Work phone	Mobile phone	
Work email address		
Do you have any restrictions on your registration (e.g. conditions or undertakings) that would prevent you from prescribing the medicines you are applying for approval for?	☐ Yes ☐ No	
If yes, provide further details of the restrictions on your registration:		

Section 2 – Patient details

Provide details of the patient this approval application relates to

Title	Surname
Given name/s	
Date of birth	
Gender ☐ Female ☐ Male ☐ Other: _____	

Initial application, amendment or renewal for a prescribing approval for (Schedule 8) psychostimulants under the *Medicines and Poisons Act 2019*

Street Address		
Town /Suburb	State	P/C

Section 3 – Diagnosis for treatment with Schedule 8 psychostimulant medicines

- ☐ Attention Deficit Disorder (ADD) Adult (≥18 years)
- ☐ ADD Child (< 4 years)
- ☐ Idiopathic hypersomnolence
- ☐ Binge eating disorder (lisdexamfetamine only)
- ☐ Treatment resistant depression
- ☐ End of life
- ☐ Other: _____ (Please provide supporting evidence of diagnosis, and clinical evidence in support of treatment.

Section 4 – S8 psychostimulant medicine proposed to be prescribed under this approval (s68)

☐ Dexamfetamine	Daily Dose: _____mg/day
☐ Lisdexamfetamine	Daily Dose: _____mg/day
☐ Methylphenidate	Daily Dose: _____mg/day

Section 5 – Supporting specialist – S8 psychostimulant treatment

Please provide details of the relevant specialist that supported the above diagnosis AND the treatment of patient with S8 psychostimulants. For example, for adult ADD – psychiatrist; treatment resistant depression – psychiatrist; eating disorder – psychiatrist or physician; idiopathic hypersomnolence – sleep specialist or respiratory physician.

Title	Surname
Given name/s	
Medical specialty	AHPRA Registration No
Work phone	Work email address
Name of location where specialist practices	
Street Address	

Initial application, amendment or renewal for a prescribing approval for (Schedule 8) psychostimulants under the *Medicines and Poisons Act 2019*

Town /Suburb	State	P/C

Section 6 – Duration of the prescribing approval (s.69 MPA)

Please specify the desired term for the prescribing approval. Applicants should note that typically prescribing approvals will not be issued for more than two (2) years.

Please specify the term of approval sought:

☐ 2 years ☐ Another term or end date, please specify:_____

Section 7 – Additional information and attachments

Provide any additional information to support your application (e.g. if an amendment application, what you are seeking to have amended).

Section 8 – Consent and Declaration

By making this application:

- I consent to Queensland Health collecting, using and disclosing my personal information for the purpose of determining this application and any matters relevant to this prescribing approval
- 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 (which may include a criminal history check). 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.

Signature	Date (DD/MM/YYYY)