Queensland Health

Application form – S2 retail licence – Initial application

August 2022

Information about this application form

This application form is to be used to apply for a licence to **retail S2 medicines** under section 75 of the *Medicines and Poisons Act 2019* (**MPA**). S2 medicines are those substances listed in Schedule 2 of the Commonwealth *Poisons Standard*.

Scope of an S2 retail licence

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. An *S2 retail licence* is a type of substance authority that may be granted under the MPA.

An S2 retail licence authorises the licence holder (including persons stated in the licence to be acting for the licence holder) to carry out the following regulated activities with the regulated substances (medicines) stated in the licence (section 65 of the MPA):

1. Buying (and possessing) stock of the substances stated in the licence.
2. Selling the substances by retail at a place stated in the licence.

Authorised way – section 31 of the MPA

All substance authorities are subject to the requirements and standard conditions prescribed by the relevant regulation, in this case the *Medicines and Poisons (Medicines) Regulation 2021* (**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 cancellation/suspension of a substance authority and/or prosecution, which may attract a significant penalty.

Requirements and standard conditions for S2 retail licences

Unless stated otherwise in the licence, 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 S2 retail licences:

- chapter 3 of the MPMR 'Standard conditions for substance authorities' – part 3 'Retail licences' and part 6 'All substance authorities'
- chapter 4 of the MPMR 'General requirements for dealings' – part 3 'Buying by giving purchase orders' and part 5 'Possessing stock for delivery'
- chapter 8 of the MPMR 'Offences' – part 2 'Secure storage systems' and part 4 'Recording and keeping information'.

1. The licence holder must not sell S2 medicines from a place (the business premises) that is within 25km of a pharmacy, calculated using the most direct route by road.
2. However, if a new pharmacy opens within 25km in a direct route from an authorised place stated in the licence during the term of the licence, for a period of up to 6 months from the day the pharmacy opens, the licence holder may sell any S2 medicines bought under the licence before the pharmacy opened (s27 of the MPMR).
3. The licence holder must not sell an S2 medicine other than in a manufacturer's pack (s28 of the MPMR).
4. The licence holder must keep an authorised place stated in the licence open for inspection during the times the place is open for carrying on business or otherwise open for entry (s29 of the MPMR).
5. For buying stock of a medicine, a licence holder and persons acting under a licence must comply with the requirements stated in chapter 4, part 3 of the MPMR 'Buying by giving purchase orders'.
6. A licence holder and persons acting under the licence must securely store medicines in accordance with the requirements stated in chapter 8, part 2 of the MPMR 'Secure storage systems'.
7. A licence holder must ensure any records required to be kept under the MPA in relation to an authorised place stated in the licence are available for inspection from the place, and if the records are kept electronically, a licence holder must ensure the records for each authorised place stated in the licence are available for inspection from the primary place of business of the licence holder (s41 of the MPMR).
8. Where a record must be made or kept, licence holders must take all reasonable steps to ensure (s224 of the MPMR):
    a. the record is kept in a retrievable form but 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.
9. A licence 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 licence holder (s42 of the MPMR):
    a. a change to an authorised place stated in the licence;
    b. a change to a relevant person stated in the licence; and
    c. another change to the licence holder's circumstances that substantially affects the holder's ability to comply with a condition of the licence.
10. Where a licence holder proposes to stop carrying out a dealing with a medicine under a licence, 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
    a. how the licence holder proposes to deal with any unused medicines.

Duration of licences

Section 69 of the MPA provides that the chief executive of Queensland Health (or delegate) determines the duration of a granted substance authority. S2 retail licences 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 licence

Fees

Licences may authorise the holder to carry out regulated activities at multiple sites, however a separate licence fee is payable for each site. In addition to the annual fee, a processing fee is payable for initial applications. The fees payable for medicines licences are in accordance with chapter 9, part 2 and schedule 19 of the MPMR.

To pay for an application, applicants must **first submit 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

Once an application is received, applicants will be given a biller code and a reference number to pay the applicable fees electronically via the BPOINT platform. To avoid delays, applicants should promptly send through their proof of payment.

Payment of the correct application fee is required for an application to be valid. See our page on fees, which contains the current schedule of fees and further information on calculating the fee payable including a simple calculator.

Assessment

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:

- whether a relevant person under the application is a fit and proper person, which may take into consideration any prior compliance history, and also the 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).

Queensland Government

Queensland Health
Medicines and Poisons Act 2019

MPA-75MRL
Version 2:08/2022
APPLICATION FOR AN S2 RETAIL LICENCE

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 licence

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 licence is to be issued to a sole trader, the **applicant** must complete the relevant person form.
(b) If the licence is to be issued to a partnership, **each partner** must complete the relevant person form.
(c) If the licence is to be issued to a body corporate or company, **an executive officer** (executive director, company secretary, chief executive officer, general manager or chief financial officer) must complete the relevant person form.

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

Section 3 – Premises where substances are to be stored and sold from

Provide details of the physical address where medicines are to be held and sold from. If more space is required, please attach further details.
***Note**: Medicines can only be stored at and sold from a location stated in the licence. Such a location cannot be within 25km of a pharmacy, calculated using the most direct route by road.*

Retail location 1

Name of shop or vessel		Premises type	☐ Shop ☐ Vessel
Street address or berth		Town /Port	P/C
HDPR/previous general poisons licence reference for this location (if applicable)			
Contact person	Phone	Email	
Does the storage at this location meet the requirements of ss198-199 of the MPMR?		☐ Yes	☐ No

Retail location 2

Name of shop or vessel		Premises type	☐ Shop	☐ Vessel	
Street address or berth		Town /Port		P/C	
HDPR/previous general poisons licence reference for this location (if applicable)					
Contact person		Phone		Email	
Does the storage at this location meet the requirements of ss198-199 of the MPMR?		☐ Yes	☐ No		

Section 4 – Medicines proposed to be sold under this licence

Provide details of the products to be sold, with reference to the schedule and name used in the latest Poisons Standard. Attach further information if required.

☐ Schedule 2 seasickness tablets only ☐ All schedule 2 medicines

Alternatively, please list specific products to be sold:

Schedule	Poisons Standard descriptor	Form	Strength	Pack size/Volume/Use
S2				
S2				
S2				
S2				
S2				
S2				

Section 5 – Duration of the substance authority

*S2 retail licences may be issued for up to two years, but a **shorter term** may be requested/ granted.*

Please specify the term of licence sought:

☐ 1 year ☐ 2 years ☐ Another term, please specify

Section 6 – Additional information and attachments

Provide any additional information to support your application

Provide/specify which attachments are attached to support this application:

- ☐ A current **company extract** from the Australian Securities and Investments Commission (ASIC)
- ☐ Details of **relevant person forms** for each person relevant to the application (partners, directors etc.)
- ☐ Other **relevant documents** 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 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 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