Queensland Health

Application form – Wholesale licence (medicines) – Renewal and/or Amendment application

March 2026

Information about this application form

This application form is to be used to apply to renew and/or amend a licence to **wholesale medicines** for therapeutic use under section 78 of the *Medicines and Poisons Act 2019* (**MPA**).

Prior to completing an application, please ensure you read the guidance – **Medicines wholesale licences – supporting information**.pdf, which

1. The scope of a wholesale licence
2. When a wholesale licence is required
3. Requirements and standard conditions for wholesale licences
4. Fees payable

To make 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 Medicines Approvals and Regulation Unit (MARU)
medicines.applications@health.qld.gov.au

Once a valid application is received, applicants will be given a reference number to **pay the applicable fees** electronically via the BPOINT platform. To avoid delays, applicants should promptly submit 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.

Queensland Government

Queensland Health

Medicines and Poisons Act 2019

MPA-75MWL | Version 1:03/2026

APPLICATION TO RENEW and/or AMEND A WHOLESALE LICENCE– MEDICINES

Collection notice: please read carefully

Queensland Health is collecting your information for the purpose of assessing and processing the application made under sections 75, 78 & 82, Chapter 3, Part 3 — (Applications for substance authorities) of the *Medicines and Poisons Act 2019*. Personal information collected by Queensland Health is handled in accordance with the *Information Privacy Act 2009*. The personal information provided by you may be disclosed to a Hospital and Health Service, Public Health Unit for the purpose of assessing the application for a substance authority, or to carry out compliance activity. Your personal information will not be disclosed to other third parties without consent unless the disclosure is authorised or required by or under law. For any questions regarding this collection notice, please contact Queensland Health's Medicines Approvals and Regulation Unit (MARU) via email: medicines.applications@health.qld.gov.au For information about how the Department of Health protects your personal information, how to access or correct your own personal information, or how to make a complaint about a breach of the privacy principles and learn how we deal with such a complaint, please refer to: Queensland Health's Privacy Policy.

Section 1 – Applicant (entity) details and application type

*Provide **current details** of the individual/organisation holding the licence (i.e. the legal entity)*

Application type	☐ Renewal - no changes **Complete sections 1, 10 & 11 only**	☐ Amendment	☐ Amend and renew

Substance authority reference number			
Name of applicant (entity/licence holder)			
Trading name (if applicable)		ACN (if applicable)	
Phone		Email	
Street address		Town/ Suburb	P/C

☐ Where applicable, attach a current **company extract (listing office holders)** purchased **from the Australian Securities and Investments Commission (ASIC)**

Section 2 –Summary of changes – (*Amendments only*)

*Provide details of the proposed **amendment**.*

☐ Adding new site/s (**Fees** will apply) | **complete Sections 1, 2, 6, 10 and 11**

☐ Changes to entity details, relevant persons of the entity (e.g. partners/directors), business structure or activities | **see Sections 1, 2, (3, 4, 5 where applicable) and 11**

☐ Updating details of an existing site, e.g. updating medicines to be supplied from that site or site supervisors | **see Sections 1, 2, 6 and 11**

Clearly describe the proposed changes requiring amendment e.g. which site is being added and when, which persons are being removed and from which sites

Sites to be removed

Site name/ Address		Date to remove	
Site name/ address		Date to remove	
Site name/ address		Date to remove	

Section 3 – Changes to entity details (if applicable)

*Provide **new** details of your entity. Note that substance authorities are not transferrable*

Entity name (e.g. individual (surname, given names), partnership, company, incorporated association)					
Trading name (if applicable)					
Postal address		Town/ Suburb		P/C	
Entity phone		Entity email			
Street address		Town/ Suburb		P/C	
Contact person		Phone		Email	

Section 4 – Changes to relevant persons for the entity (if applicable) (S76 MPA)

Partners/Executive officers (directors, CEO etc.) to add or update (attach relevant person form for

*To add or update details for relevant persons e.g. partners, executive officers of a body corporate etc., indicate the changes below and attach a **'Details of relevant person**' form (MPA-76) for the person to be added/updated.*

Name		◯ Add new	◯ Update
Name		◯ Add new	◯ Update

Partners/Executive officers (directors, CEO etc.) to remove

To remove a relevant person, provide details below. If more space is required, please attach further details.

Name		☐ Remove
Name		☐ Remove

Section 5 – Changes to business structure and activities

Clearly describe any changes to your business structure, including relationships to other involved entities, such as sister/parent entities. Attach a diagram if needed

Clearly describe any changes to your intended business activities, providing an updated flow chart to demonstrate the parties involved and who will undertake what steps or actions/activities

Have you obtained, surrendered, or are you applying for or surrendering, any relevant Commonwealth or interstate licences or permits?	◯ Yes	◯ No

If yes, provide details including licence numbers

APPLICATION TO RENEW and/or AMEND A WHOLESALE LICENCE– MEDICINES

TO ADD OR UPDATE MULTIPLE SITES, PLEASE COMPLETE AN ADDITIONAL SITE ATTACHMENT FOR *EACH SITE* TO BE ADDED OR UPDATED, AND ATTACH TO YOUR APPLICATION

Section 6 – Add new or update existing sites (if applicable) (s64(b)

Provide details of the new premises to be added or the details of proposed changes to the physical address where substances are to be stored and sold from.

◯ Add new site	◯ Update existing site details

Name of entity conducting operations (e.g. storing, picking, transporting) at/from this location	

Site address		Town/ Suburb		P/C	

Explain any updates to your storage location/s.

Substances proposed to be supplied from this location (s(64(d) MPA)

- *For adding **new** sites, provide details of the substances to be supplied.*
- *For **updates to existing** sites, **specify all classes of medicines proposed to be supplied** at this site (including existing), as listed in the latest Commonwealth Poisons Standard.*

☐ S3 or S4 medicinal cannabis	☐ S8 medicinal cannabis	☐ S3 or S4 Nicotine
☐ S2, S3 or S4 ARTG **registered** medicines	☐ S8 ARTG **registered** medicines	
☐ S4 Veterinary medicines	☐ S8 Veterinary medicines	

☐ Other unapproved medicines (please provide details)

Supervisor details

*Provide **details** of the supervisor who will be responsible for overseeing or supervising for this site. **Each nominated person must complete a Details of relevant person form**. Supervisors are named on the licence, and notification must be made when a supervisor changes for a site. Attach details for additional supervisors.*

Supervisor name		Phone		Email	
Position/role title		Entity			

Third Party Distributor Information

Will you be using a third-party distributor at this location?	◯ Yes	◯ No

Name of third-party distributor operating at this premises:	

YOU MUST ATTACH AN ASIC EXTRACT FOR ANY THIRD-PARTY DISTRIBUTOR (NEW SITES ONLY)

If supplying unapproved medicines (e.g. medicinal cannabis) explain in detail how direct control will be maintained over the medicines

Substance Management Plan (SMP) (s93 MPA, Chapter 6 and Schedule 17 MPMR)			
Note: Copies of SMP and SRMP are not required to be submitted with your application.			
You must have an **SMP** for **this location**, **in the name of your entity, signed by each executive officer of your entity,** that meets the Departmental Standard – Substance Management Plans for Medicines			
Changes to the Security Risk Management Plan (SRMP) (S71 MPMR)			
You must have an **SRMP** for **this location in the name of your entity** that complies with the Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8 (the **Code**)			
Has the SRMP been prepared with a registered security consultant?		◯ Yes	◯ No
Name of registered security consultant		Security consultant number	
Readiness			
Date this location will be ready for an inspection:	☐ Now	Date (within a Maximum of 6 weeks)	

Section 7 – Changes to supply of substances by wholesale (s64(d) MPA)

*Provide details of the classes of persons to whom you intend to supply the substances. Select all that apply. Note: for **unapproved medicines (e.g. medicinal cannabis, nicotine**) you will be limited to supply to medical practitioners, nurse practitioners and pharmacists, or to clinical trials, as per TGA rules for supply of unapproved medicines.*

◯ Add new	◯ Remove existing

Provide a brief description of the changes to class of persons

☐ Manufacturers	☐ Podiatrists
☐ Wholesalers	☐ Optometrists
☐ Other substance authority holders	☐ Nurse practitioners
☐ Primary producers	☐ Midwives
☐ Veterinary surgeons	☐ Other health practitioners, please specify
☐ Pharmacists	
☐ Doctors	☐ Other persons, please specify
☐ Dentists	

Section 8 – Additional information and attachments

Provide any additional information to support your application

The following documents **must be attached** to support this application

For amendment applications to change **entity details (section 3):**

☐ A current **company extract (listing office holders)** from the Australian Securities and Investments Commission (ASIC) (unless an individual/sole trader or partnership) for the applicant.
To **purchase** an extract: https://connectonline.asic.gov.au/RegistrySearch/faces/landing/SearchRegisters.jspx

For amendment applications to change **relevant person details (section 4):**

☐ **Details of relevant person forms** for an Australian-based director, or each partner, or the sole trader

For amendment applications to change **business structure or activities (section 5):**

☐ Diagram of **business structure**/model

☐ **Flow chart** of business activities demonstrating who undertakes what actions/activities

☐ If applying to wholesale unregistered medicines, or medicinal cannabis, provide evidence of Commonwealth **sponsorship**, Commonwealth or interstate licence, approval or permit (or evidence of application to these authorities)

For amendment applications to **add or change existing sites (section 6):**

☐ **Details of relevant person forms** for each new supervisor, clearly identifying which locations the supervisor is responsible for

☐ **Self-audit checklist** completed for each new site

☐ If using a third-party distributor, provide an ASIC **current company extract** and **Details of relevant person form** for a director of the **third-party distributor**

☐ Other **documents** please specify

Section 9 – Important information

- If making an amendment application, you must provide all relevant documents to demonstrate or justify the changes.
- Applicants must have a substance management plan **in their own entity name** for **each premises to be licensed**.

*Note: Copies of **SMP** and **SRMP are not required** to be submitted with your application but must be available to be produced upon request from a Queensland Health or Hospital and Health Service Inspector or other authorised person, and during compliance activities.*

- Applicants must also have undertaken a security risk assessment **for each premises** and, if proposing to wholesale S8 medicines including medicinal cannabis, this assessment must be undertaken for you (not for another entity) by a registered security consultant.
- Applicants must complete and submit a self-audit checklist for **each premises** proposed to be licensed.

Wholesalers using distributors

You must have the following documents ready and available to be produced upon request from a Queensland Health or Hospital and Health Service inspector or other authorised person, and during compliance activities:

- If updated, a revised copy of a Substance Management Plan (SMP) in your entity's name (not a distributor's SMP) or an additional SMP for any new premises
- If updated, a revised copy of a Security Risk Management Plan (SRMP) in your name (not a distributor's SRMP) or an additional SRMP for any new premises
- Self-audit checklist completed by your entity (not by a distributor) for any new premises
- Any documents mentioned within the above documents (e.g., standard operating procedures (SOPs)), which have not been incorporated into the document.

Note: Applications made that do not have these documents ready when required will be decided based on the information available to the decision maker

An application to amend a licence is taken to be a Notification of particular changes affecting authority under section 42 of the MPMR **if it is given within 5 business days after the change in circumstances happen.**

Section 10 – Duration of the substance authority (s69 MPA)

Medicines wholesale 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 11 – Consent and declaration

By making this application:

- ☐ I declare that I have authority to make this application on behalf of the applicant.
- ☐ I declare that our entity's SMPs and SRMPs have been prepared in our name (the name of the applicant) and comply with the requirements outlined in the MPA, MPMR and the Code.
- ☐ 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.
- ☐ 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 [s.96 MPA].

Full name of applicant (Director, partner or other authorised representative)	Position of applicant or authorised representative

Signature of applicant, partner or director (where the applicant is a body corporate or another entity)	Date (DD/MM/YYYY)

Please ensure all sections are answered in full, and all required supporting documents are attached. Incomplete applications will be returned.

Clear form