Queensland Health

Medicines wholesale licence – supporting information for applicants

March 2026

Information about applying for a wholesale licence

This guidance is provided to support applicants seeking to apply for a licence to **wholesale medicines** for therapeutic use under section 75 of the *Medicines and Poisons Act 2019* (**MPA**). Medicines are schedule 2, 3, 4 and 8 substances as listed in the Commonwealth *Poisons Standard* (section 11 of the MPA).

To wholesale poisons, fumigants, pesticides or prohibited substances for non-therapeutic use, please navigate to: https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/poisons/forms-fees

Interstate licence holders (corresponding law wholesalers)

Persons who are permitted to supply medicines by wholesale under a corresponding law (e.g. the holder of a wholesaler's licence granted under the NSW *Poisons and Therapeutic Goods Act 1966*) **do not** require a wholesale licence under the MPA to possess and supply the same medicines in Queensland, provided the corresponding law wholesaler (Schedule 14, Part 2 of the Medicines and Poisons (Medicines) Regulation 2021 (**MPMR**):

1. complies with any conditions of their licence/permission under the corresponding law;
2. only arranges the delivery of the medicines to an authorised person in Queensland; and
3. does not store the medicines in Queensland, including at a storage facility operated by a third party.

Where a corresponding law wholesaler does not meet these conditions, a wholesale licence granted by Queensland Health under the MPA is required. Check with Medicines Approvals and Regulation Unit (MARU) via medicines.applications@health.qld.gov.au if you are unsure.

Scope of a wholesale 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. A *wholesale licence* is a type of substance authority that may be granted under the MPA.

Section 64 of the MPA provides that a wholesale 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:

1. Buying stock of the regulated substances stated in the licence.
2. Possession of the regulated substances at the premises stated in the licence.
3. Possession of the regulated substances for transportation to a place where a person is authorised, or where it is not unlawful for a person, to possess the substances.
4. Supply of the regulated substances by wholesale to:
    a. if the licence states a class of persons to whom the substances may be supplied - a person who is a member of the class; or
    b. otherwise - a person who is authorised, or for whom it is not unlawful, to carry out a regulated activity with the regulated substances.
5. Disposal of waste from the regulated substances.

Authorised way – section 31 of the MPA

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 wholesale 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 wholesale licences:

- 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 4 'Supplying stock', part 5 'Possessing stock for delivery' and part 11 'Disposing of waste from diversion-risk medicines'
- Chapter 5 of the MPMR 'Special requirements for dealings' – part 5 'Wholesale representatives' 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. A licence holder must ensure stock of a medicine is only handled by an appropriately qualified adult employed by the licence holder (s70 of the MPMR).
2. A licence holder must comply with, and take all reasonable steps to ensure a person employed by the licence holder complies with, the *'Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8'* published by the Therapeutic Goods Administration (s71 of the MPMR).
3. 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'.
4. For supplying stock of a medicine, a licence holder and persons acting under a licence must comply with the requirements stated in Chapter 4, Part 4 of the MPMR 'Supplying stock', including that a licence holder must supply stock of a medicine only if (ss56-59 of the MPMR):
    a. the supplier reasonably believes that the buyer of the medicines is authorised under the MPA, or under a corresponding law or another law to give a purchase order or otherwise buy the stock of medicines; and
    b. the buyer gives the licence holder a compliant purchase order for the medicines.
5. A licence holder must not supply stock of a medicine to a buyer unless the container of the medicines and the labelling on the medicine complies with the requirements of the Poisons Standard or an alternative way approved, or taken to be approved, by the chief executive of Queensland Health (or delegate) (s73 of the MPMR).
6. A licence holder must not supply a medicine on an expired purchase order (more than one year old), or where the licence holder reasonably suspects that a purchase order has been unlawfully obtained or prepared, cancelled, fulfilled or otherwise doesn't comply with the MPA (s60 of the MPMR).
7. A licence holder must give the buyer an invoice or other notice stating the following information (s61(1) of the MPMR):
    a. a unique identifier for the invoice;
    b. the date of the supply;
    c. the name and address of the buyer;
    d. if the stock is delivered – the place to which the stock is delivered;

e. the details of the buyer's authorisation or permission to buy the stock;
f. the name, form and strength of the medicine supplied; and
g. the amount of stock of the medicine supplied.

8. A licence holder must keep a copy of the invoice or a record of the details contained in the invoice (s61(2) of the MPMR).
9. When a licence holder supplies the stock on a purchase order, the licensee must (S62 of the MPMR):
    a. mark the purchase order in a way that shows the order has been supplied and, if applicable, delivered; and
    b. keep a copy of the marked purchase order.
10. For transporting stock of a medicine, a licence holder and persons acting under a licence must comply with the requirements stated in Chapter 4, Part 4 of the MPMR 'Supplying stock' and Part 5 'Possessing stock for delivery', including that a licence holder must ensure delivery of the stock is to the street address stated on the purchase order for the stock (ss67 and 78 of the MPMR).
11. A licence holder must not deliver, or arrange to deliver, stock of a medicine to a buyer unless (ss64 and 65 of the MPMR):
    a. the medicine is sealed in a securely closed package that is likely to show if the package breaks or anyone tampers with it; and
    b. the package is clearly labelled with the name of the buyer and the street address for delivery stated on the purchase order for the stock; and
    c. if the medicine is an S8 medicine:
        i. the package is not mixed with anything other than S8 medicines; and
        ii. the package has no label or mark on it that indicates it contains an S8 medicine.
12. A licence holder may engage a carrier only if the licence holder reasonably considers the carrier is capable of complying with the requirements of the MPMR (s66 of the MPMR), such as maintaining temperature limits for the safe storage of stock, obtaining receipt of delivery and not leaving stock unattended except in a secure area (ss76-78 of the MPMR) and those requirements in Chapter 8, Part 2, Division 4 'Carriers'.
13. Before arranging with the carrier to deliver the stock, the licence holder must notify the carrier of the temperature limits for the stock that are recommended by the manufacturer of the medicine (s66(2) of the MPMR).
14. When delivering or arranging delivery of stock of an S8 medicine to a buyer, the licence holder must obtain and keep a signed notice from the buyer, or from an adult acting or purportedly acting on behalf of the buyer at the buyer's street address, acknowledging receipt of the delivery. If the licence holder has not received a signed notice of receipt within 5 business days after the date of delivery, the licence holder must notify the chief executive of Queensland Health (or delegate) about the buyer's failure to confirm receipt of delivery (ss68-69).
15. For disposing of waste from a diversion-risk medicine, the licence holder and persons acting under the licence must comply with the requirements stated in Chapter 4, Part 11 of the MPMR 'Disposing of waste from diversion-risk medicines' (see Schedule 2, Part 3 of the MPMR for the list of diversion-risk medicines).
16. Where a licence holder employs wholesale representatives (s70 of the MPMR):
    a. the licence holder must make and keep records showing the details of any stock given to a wholesale representative;
    b. the licence holder must ensure each wholesale representative is aware of requirements under the MPA applying to the supplier and representative; and

c. the representatives must comply with the requirements of chapter 5, part 5 of the MPMR 'Wholesale representatives' and the conditions of the licence.

17. 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'.
18. A licence holder and persons acting under the licence must establish and maintain a medicines register, to track all the regulated activities with medicines under the licence until medicines are completely used or destroyed, in accordance with Chapter 8, Part 2, Division 3 of the MPMR 'Medicines registers'.
19. A licence holder, including any wholesale representatives employed by the holder, must report the loss or theft of a diversion-risk medicine that was in the possession of the licence holder immediately before the loss or theft, as soon as practicable, but no later than the end of the next business day, to the chief executive of Queensland Health (or delegate) in the approved form and to the Queensland Police Service (s226 of the MPMR).
20. 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).
21. 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.
22. 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.
23. 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
    d. how the licence holder proposes to deal with any unused medicines.

Information about wholesale licences

Wholesale representatives

Wholesale representatives who act as an agent for the licence holder, may possess and supply S2, S3, or S4 medicines (other than monitored medicines) in starter packs to authorised practitioners in accordance with the '*Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8*' and the other requirements specified in Chapter 5, Part 5; and Schedule 14 of the MPMR.

Wholesale representatives must not possess more than is reasonably necessary to meet the business needs of the representative for a 6-month period.

Substance management plans

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. Applicants for wholesale licences must have their own SMP that meets the requirements specified in s93 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.

Poisons licences

Applications for wholesale licences for medicines (for therapeutic purpose) are considered separately from licences for poisons, fumigants, pesticides and prohibited substances (non-therapeutic) due to the separate regulations and departmental standards that apply.

Where an application is made, or a licence is held, to manufacture or wholesale a poison at the same place as S2, S3 or S4 medicines are to be wholesaled, a medicines wholesale licence is still required, but an additional fee is not payable.

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. Wholesale 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 (in this case, the wholesale licensee) 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.

Initial applications 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. The fees payable for medicines licences are in accordance with Chapter 9, Part 2; and Schedule 19 of the MPMR. Where a fee has been paid for a licence to manufacture or wholesale poisons at the same site (under the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 (MPPSR)), no fee is payable for an S2, S3 or S4 medicines wholesale licence.

There is a fee payable per site per year for an initial application for a wholesale licence for an S8 medicine and a separate fee payable per site per year for an initial application for a wholesale licence for an S2, S3 or S4 medicine. Where a wholesale licence covers both S8 medicines and S2, S3 or S4 medicines at a site, then both fees are payable.

In addition to the annual fees, a processing fee is payable for initial applications. Again, where a wholesale licence covers both S8 medicines and S2, S3 or S4 medicines, then two fees are payable.

How to apply

To make an application, applicants must **first submit** the **Application form - wholesale licence (medicines) - initial application**, 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 an application reference number to **pay the applicable fees** electronically via the BPOINT platform.

Applicants should enter the following details:

- Payment of Medicines and Poisons Act 2019 Fees – Wholesale licence (Medicines)
- Application reference number: Your application number as advised to you by us (e.g. A*********)
- Contact name: Your name and the name of the entity applying for the licence (licensee)
- Contact phone / email: Contact details of the person authorised to submit the application

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.

Deciding an application

In determining the application, the matters described in section 76 of the MPA may be taken into consideration.

To inform the decision maker on these matters, they may consider the following 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).

Applying for an amendment of a wholesale 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. **If a new site is added as an amendment to the licence, then an additional fee is payable for the period remaining until expiry.**

There is a fee payable per site per year for an amendment application for a wholesale licence for an S8 medicine and a separate fee payable per site per year for an amendment application for a wholesale licence for an S2, S3 or S4 medicine. Where a wholesale licence covers both S8 medicines and S2, S3 or S4 medicines at a site, then both fees are payable per year per site.

How to apply

To make an application, applicants must **first submit** the **Application form - wholesale licence (medicines) - renewal and/or amendment** 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, if an additional site is to be added to the licence, applicants will be given an application 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.

Applying for a renewal of a wholesale licence

Timing

A renewal application must be made using the Application Form – Wholesale licence (medicines) – Renewal application form: (https://www.health.qld.gov.au/__data/assets/pdf_file/0017/1111490/form-wholesale-medicines-renewal.pdf) within the period starting 90 days before the term of the substance authority ends (s82(2) of the MPA). In exceptional circumstances, a late application may be accepted up to 30 days after the term of the current authority ends (s82(3) of the MPA).

If an application to renew a substance authority is made on time with payment (or a late application accepted with payment), the authority continues in force until the application is decided or taken to have been withdrawn (s85 the MPA).

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).

Fees

Licences may authorise the holder to carry out regulated activities at multiple sites, however a separate licence fee is payable for each site. The fees payable for medicines licences are in accordance with Chapter 9, Part 2 and Schedule 19 of the MPMR.

There is a fee payable per site per year for a renewal application for a wholesale licence for an S8 medicine and a separate fee payable per site per year for a renewal application for a wholesale licence for an S2, S3 or S4 medicine. Where a wholesale licence covers both S8 medicines and S2, S3 or S4 medicines at a site, then both fees are payable.

How to apply

To make an application, applicants must **first submit** the **Application form - wholesale licence (medicines) - renewal and/or amendment** 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 an application reference number to **pay the applicable fees** electronically via the BPOINT platform.

Applicants should enter the following details:

- Payment of Medicines and Poisons Act 2019 Fees – Wholesale licence (Medicines)
- Application reference number: Your application number as advised to you by us (e.g. A*********)
- Contact name: Your name and the name of the entity applying for the licence (licensee)
- Contact phone / email: Contact details of the person authorised to submit the application

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.

Applying to renew and amend a wholesale licence

Fees

Where applying to renew a licence but also make amendments to add or remove a site, then the relevant fees will be calculated for you. A separate fee may be taken for the renewal and for the amendment, or a part refund may be required, depending on the timing and nature of the amendment.