

Medicines and Poisons Act 2019

Factsheet – current as at September 2021

Wholesale suppliers – medicines

What is wholesale supply?

The *Medicines and Poisons Act 2019* (MPA) regulates the wholesale supply of medicines, poisons and prohibited substances (collectively ‘regulated substances’) in Queensland. Under the *Medicines and Poisons (Medicines) Regulation 2021* (MPMR), wholesale supply is taken to mean: the supply of stock of a medicine to a person who is buying the stock for the purposes of retail on-sale or use by, or in connection with, carrying on a business, industry, profession or trade.

Under the MPA, ‘stock’ means—

- (a) a regulated substance that is intended for supplying a place or a person who is authorised to carry out a regulated activity with the substance; or
- (b) a regulated substance that is not sold or dispensed to a particular person.

Who is a wholesale supplier?

A wholesale supplier is anyone authorised under the *Medicines and Poisons Act 2019* (MPA) or permitted under another Act or a corresponding law¹ to supply stock of medicines. This includes:

- Wholesale licence holders – persons granted a licence to wholesale a medicine under the MPA;
- Manufacturing licence holders – persons granted a licence to manufacture a medicine under the MPA;
- Commonwealth law manufacturers – persons permitted to manufacture a medicine under a Commonwealth law;
- Corresponding law wholesalers – persons permitted under a corresponding law to supply a medicine by wholesale, which includes interstate wholesalers; and
- Pharmacists, including intern pharmacists.

¹ A corresponding law being:

(a) the Commonwealth Therapeutic Goods Laws, and the applied therapeutic goods provisions, under the *Therapeutic Goods Act 2019*; or

(b) a law of another jurisdiction that provides for, or provided for, the same or similar matters as the MPA.

Do all wholesale suppliers need a Queensland wholesale licence?

No. The following persons do not need a licence in the circumstances described:

- Commonwealth law manufacturers do not need a Queensland licence to wholesale the substances authorised by their Commonwealth permission (licence/approval/permit etc.), provided they comply with all the conditions of their permission.
- Interstate (corresponding law) wholesalers do not need a Queensland licence to wholesale directly into Queensland, i.e. the medicine must not be stored at a place in Queensland or arranged to be collected from a storage facility located in Queensland.
- Queensland licenced manufacturers do not need a separate wholesale licence to supply the medicines produced.
- Pharmacists do not need a licence to supply stock from a pharmacy to an approved person, other than a pharmacist, who is authorised to give a purchase order for the medicine or administer the medicine.
- Pharmacists do not need a licence to supply stock to another pharmacist but only in specific circumstances:
 - to urgently fill a shortage of stock held by the other pharmacist; or
 - as part of an arrangement with the pharmacist to prevent the stock from expiring; or
 - for satisfying an order made by a client of the other pharmacist.

Any supply beyond what is permitted in these circumstances will likely require a Queensland wholesale licence.

How does the scheme regulate wholesale suppliers?

The obligations for wholesale suppliers of medicines remain the same, irrespective of being licenced or authorised in another way, with the exception of medicated feed due to its unique circumstances – for further information see ‘Medicated feed– factsheet’.

Wholesale suppliers should ensure that they adhere to all requirements applying to them, in particular those in relation to buying and supplying stock of medicines, transporting medicines, disposal of medicine waste, secure storage of medicines, recording and keeping information, and reporting losses and other particular matters. These requirements are in Chapter 4 Parts 3, 4, 5 and 11 and Chapter 8.

In summary, these requirements include:

- Persons must buy medicines on a purchase order that contains the particulars in the regulations, is made and sent securely to prevent fraud or tampering, is signed or otherwise has a buyer’s unique identifier, and is given before purchase.

- Wholesale suppliers must implement measures to ensure the supply and purchase of medicines are restricted to persons authorised or otherwise permitted under the Act or another law to buy stock.
- Suppliers must only supply medicines on a purchase order that meets the requirements of the regulation, mark and keep copies of purchase orders and provide an invoice or other document with the specified particulars.
- Stock must be stored and supplied in compliance with the 'Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8', in manufacturer's packs, and labelled in accordance with the Poisons Standard.
- Medicines must only be delivered in secure packaging to the street address on the purchase order and, for S8 medicines, a notice of receipt must be obtained, or the chief executive notified that the buyer failed to provide one. S8 medicines must not be mixed with anything other than S8 medicines.
- Wholesale suppliers must ensure that storage and transport of medicines occur in a manner that prevents access to unauthorised persons and maintains the stock of the medicines within specified temperature limits. For Schedule 8 medicines, storage must meet the requirements of the departmental standard 'Secure storage of S8 medicines'.
- Wholesale suppliers must not engage a carrier to deliver stock of a medicine unless the supplier reasonably considers the carrier is capable of complying with the requirements for possessing for delivery in the regulation, and before arranging with the carrier to deliver the stock, the supplier must notify the carrier of the temperature limits for the stock that are recommended by the manufacturer of the medicine.
- Waste of diversion-risk medicines must be separated from other medicines, but stored securely and clearly marked for destruction until such time as the medicines can be properly disposed of, if authorised, or otherwise given to a person authorised to dispose of waste.
- Wholesale suppliers must ensure details of medicines bought, sold and disposed of are recorded in an appropriate manner. Specifically, a medicines register, which records all dealings in relation to S8 medicines, must be established. The medicines register may be electronic or paper based and must include details such as date, name, form, strength and amount of medicine, nature of dealing etc. to be able to reconcile the amount of medicine received, supplied or disposed of.
- Particular incidents must be reported to the chief executive of Queensland Health and to the police service, including for lost and stolen diversion-risk medicines, and attempts made by persons to obtain diversion-risk medicines with unlawfully made or obtained purchase orders.

What is a substance management plan and do wholesale suppliers need to have one?

A substance management plan (**SMP**) is a document setting out how known and foreseeable risks associated with any dealing with a regulated substance are to be managed at, or in connection with, the regulated place. SMPs must comply with the Departmental Standard: '*Substance management plans for medicines*'. To support persons to meet this new

requirement, a transitional period of one year has been afforded to develop and implement a compliant SMP and guidelines and templates for SMPs will be made available.

An SMP for medicines is required for any place specified as a regulated place under the MPMR. Accordingly, wholesale suppliers that hold stock of medicines in Queensland will be required to prepare an SMP, as an SMP is required for a 'place where a medicine is stored for supply by wholesale', 'a place where a medicine is manufactured under a manufacturing licence', 'a community pharmacy' and 'a specified pharmacy'.

Can aspects of wholesale supply be outsourced, and do they need a licence?

Aspects of the supply process may be outsourced to third parties without that party requiring a licence provided that certain requirements are met:

- Medicines can only be stored at an authorised location i.e. at a place stated in a licence/approval/permit etc. (for licensees or Commonwealth law manufacturers) or a pharmacy (for pharmacists); and
- Medicines can only be handled by employees (includes contractors) of the wholesale supplier.

Where aspects of the wholesale supply process are outsourced, the wholesale supplier is still responsible for ensuring that the relevant requirements are met, although the third party must comply with the requirements of the MPMR. Importantly, third parties must also comply with any SMP that applies.

Key points for wholesale suppliers

- Wholesale supply is the supply of stock of a medicine to a person who is buying the stock for the purposes of retail on-sale or use by, or in connection with, carrying on a business, industry, profession or trade.
- Not all wholesale suppliers must have a Queensland wholesale licence, persons may be authorised in other ways.
- Irrespective of how a person is authorised, the obligations for wholesale suppliers under the MPMR, e.g. buying, supplying and disposing of waste, remain the same, with the exception of medicated feed.
- You must prepare a substance management plan (SMP) setting out how known and foreseeable risks associated with any dealing with a regulated substance are to be managed at, or in connection with, any place where a medicine is stored for supply by wholesale, including manufacturing premises and pharmacies.
- Aspects of the wholesale process may be outsourced to third parties in some circumstances; however, wholesale suppliers must ensure that all obligations are met. Both wholesale suppliers and third parties must comply with the regulatory requirements including any substance management plan.

Associated guidance documents

- When is a wholesale licence required – factsheet
- Carriers, transport and logistics – factsheet
- Substance management plans – factsheet
- Medicinal cannabis wholesalers – factsheet
- Wholesale representatives – factsheet
- Commonwealth law manufacturers – factsheet
- Medicated feed – factsheet
- Categories of medicines and dealings – factsheet
- Substance authorities – factsheet
- Wholesale licence (medicines) – initial application form and guideline
- Wholesale licence (medicines) – renewal application form and guideline

Further information

For further information, contact the Healthcare Approvals and Regulation Unit (HARU):
HARU@health.qld.gov.au.