

Medicines and Poisons Act 2019

Factsheet – current as at September 2021

When is a wholesale licence required under the *Medicines and Poisons Act 2019*

Purpose

The purpose of this fact sheet is to clarify when a licence is required under *the Medicines and Poisons Act 2019* (MPA) by entities involved in the manufacture, supply, distribution and delivery of stock of medicines, poisons and prohibited substances.

Background

The MPA and regulations provide a revised framework for manufacturing and wholesaling licences in Queensland. The new scheme seeks to reduce duplication through recognition of Commonwealth and interstate licences (including permits, approvals and other permissions):

- holders of Commonwealth manufacturing licences/permits/approvals etc. (granted by the Therapeutic Goods Administration (TGA), Australian Pesticides and Veterinary Medicines Authority (APVMA) or Office of Drug Control (ODC)) do not need to hold a Queensland licence to wholesale products manufactured under that Commonwealth authority to the extent that substances authorised under that authority are manufactured at the same premises and within any conditions of that authority; and
- holders of interstate wholesale licences may sell products directly into Queensland to authorised buyers, provided the stock is not stored in Queensland.

In the new scheme, licences and approvals are collectively known as substance authorities and include manufacturing licences, wholesale licences, retail licences and general approvals (see section 61 of the MPA).

When is a licence required?

To understand when a licence is required, it is important to understand what is meant by the term 'sell' under the MPA.

Sell, a regulated substance, includes attempt to sell the substance or make the substance available for sale.

Accordingly, advertising or listing a product online, or arranging to have a product shipped direct from a supplier to a buyer is considered 'selling'. It is not relevant who 'owns' the stock or *how* the stock is offered for sale.

Stock stored in Queensland

In accordance with the above principles, the following information seeks to clarify who is required to hold a substance authority, where stock is stored in Queensland, and the obligations that apply:

1. The company that is selling the stock (doing the transaction) must hold the Queensland wholesaling licence.
2. Any premises where the stock is stored must be on the licence and fees are payable for each site.
3. The licensee is responsible for meeting the requirements/obligations under the MPA, including where these are carried out by a third party, such as storage and security, transport and delivery, customer validation, receipting, record keeping and reporting.
4. A wholesale licensee must have documented in their substance management plan how risks applicable to wholesaling (such as risks to the quality, security and traceability of goods) will be managed, including who may carry out what actions and in which circumstances.
5. Any third-party holding stock or carrying out a wholesaling function on behalf of a licensee must also comply with the conditions of the licence and the licensee's substance management plan.
6. Where substances have been purchased by a client (on a purchase order) and are being transported from a wholesale premises to the delivery address, no additional licence or general approval is required by the entity transporting the stock, as carriers are authorised to possess regulated substances when delivering the stock from one place to another.
7. If a carrier is engaged, the entity engaging the carrier has a responsibility to confirm the carrier can meet their obligations, including that stock must not be left unattended other than in a secure area, and that stock can only be delivered to the physical address on the purchase order.
8. **As part of delivery**, which may take multiple days, stock may be taken from one vehicle to another along the way, and the carrier may take stock off the vehicle to a secure area during the transit, awaiting connection, but stock cannot be transported to an unlicensed premise pending purchase.

Stock stored interstate/overseas

Stock stored interstate or overseas may be supplied into Queensland to any person authorised under the MPA to buy the stock. Typically, the company supplying the stock will

hold either an interstate licence or a Commonwealth licence (or other authority), or both. Where the company supplying the stock from interstate or overseas is based in Queensland but does not hold the relevant interstate or Commonwealth licence, that company will require a Queensland wholesale licence, despite not holding stock in Queensland.

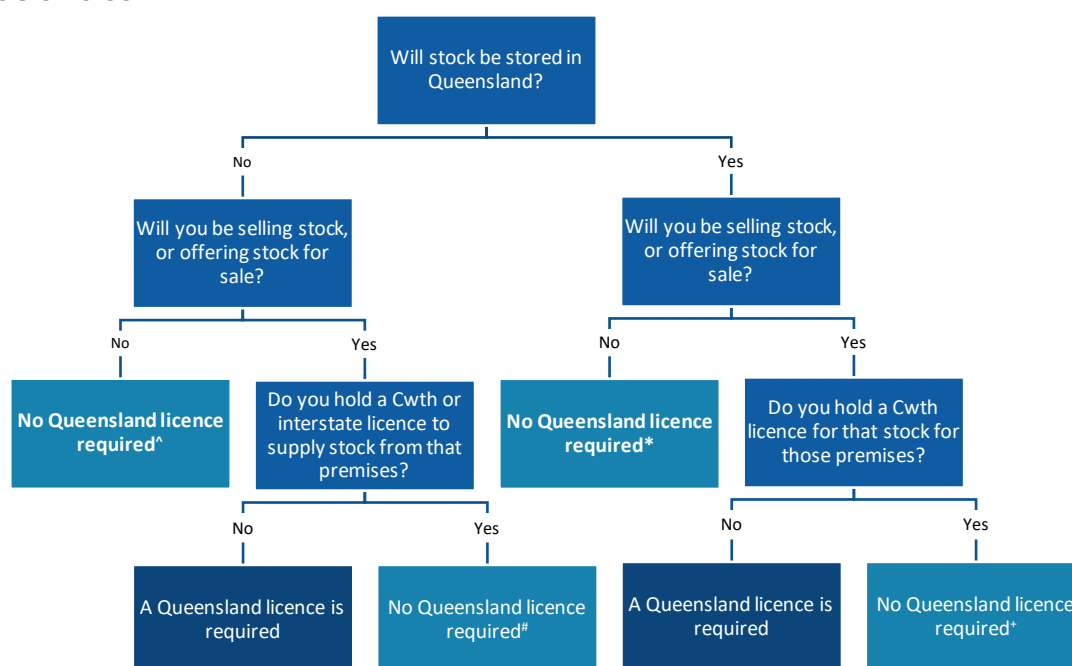
What this means is that, **any Queensland-based company that is selling stock, must be licenced**, including companies operating solely online.

Your circumstances

Queensland Health understands that businesses operate in many different ways, carrying out some or all of the functions of supply, from single or multiple premises both here in Queensland and interstate. To help determine whether a Queensland licence is required in your particular circumstances, see the below decision tree and example scenarios.

It is important to note that, **all entities involved in the supply chain must comply with the requirements of the MPA and applicable regulations**, even where an entity is not required to hold a Queensland licence.

Decision tree



[^] You may be permitted to supply stock into Queensland from interstate/overseas under another entity's licence or authority (e.g. APVMA or ODC permit) – check with licensee/authority holder.

[#] You may supply stock into Queensland from interstate/overseas under your licence or authority.

^{*} You may store and deliver stock from your premises under another entity's licence, provided the premises are listed on the licence and the persons handling the stock are employees (or contractors) of the licensee.

⁺ You may supply stock permitted under your Commonwealth licence or authority from your premises.

Example scenarios

Below are scenarios which consider different business models and circumstances. The following codes have been used for substance authority types.

ML – Manufacturing licence (Queensland); ML-C – Manufacturing licence/permit etc. (Commonwealth); WL – Wholesale licence (Queensland); WL-I – Wholesale licence (interstate); NA – No Substance Authority

#	Circumstance/outcome	Substance authority
1	Company A is located in Queensland, stock is stored at their Queensland premises, stock is sold by Company A interstate only.	
	<ul style="list-style-type: none"> Company A must hold a Queensland wholesale licence. 	WL
2	Company B is located in Queensland, stock is stored interstate at Company C's premises, stock is sold by Company B in Queensland and interstate.	
	<ul style="list-style-type: none"> Company B will need to hold a Queensland wholesale licence if they do not hold an interstate licence (from the state where stock is stored). 	WL/WL-I
	<ul style="list-style-type: none"> Company C does not need to hold a Queensland wholesale licence but may require an interstate licence. 	WL-I
3	Company D's head office is located interstate and holds an interstate wholesale licence, stock is stored at their Queensland premises, stock is sold both in Queensland and interstate.	
	<ul style="list-style-type: none"> Company D must hold a Queensland wholesale licence. 	WL
4	Company E is located in Queensland, stock is stored at Company F's premises, stock is sold by Company E both in Queensland and interstate.	
	<ul style="list-style-type: none"> Company E must hold a Queensland wholesale licence. 	WL
	<ul style="list-style-type: none"> Company F does not require a substance authority, but the premises must be listed on Company E's wholesale licence. Company F is only authorised to hold stock that Company E sells (under company E's licence). 	NA
5	Company G is located interstate, stock is stored at their premises interstate, stock is sold both in Queensland and interstate.	
	<ul style="list-style-type: none"> Company G does not require a Queensland wholesale licence but an interstate wholesale licence. 	WL-I
6	Company H is located interstate, stock is stored at Company I's Queensland premises, stock is sold by Company H both in Queensland and interstate.	

#	Circumstance/outcome	Substance authority
	<ul style="list-style-type: none"> Company H must hold a Queensland wholesale licence. 	WL
	<ul style="list-style-type: none"> Company I does not require a substance authority, but the premises must be listed on Company H's wholesale licence. Company I is only authorised to hold stock that Company H sells. 	NA
7	Company J is located interstate, stock is stored at three of Company K's Queensland premises, stock sold by Company J both in Queensland and interstate.	
	<ul style="list-style-type: none"> Company J must hold a Queensland wholesale licence with all three premises listed on the licence (fees paid for each individual site). 	WL
	<ul style="list-style-type: none"> Company K does not require a substance authority, but all three premises must be listed on Company J's wholesale licence. Company K is only authorised to hold stock that Company J sells. 	NA
8	Company L is a logistics company that handles warehousing and distribution for three companies, M, N and O, who each sell their own products. Company L has two premises. Companies M and N hold stock at both premises, while Company O holds stock at only one of the premises.	
	<ul style="list-style-type: none"> Company M must hold a Queensland wholesale licence with both premises listed on the licence. Company M may transfer stock between the premises (with records kept, to ensure traceability). 	WL
	<ul style="list-style-type: none"> Company N must hold a Queensland wholesale licence with both premises listed on the licence. Company N may transfer stock between the premises (with records kept to, ensure traceability). 	WL
	<ul style="list-style-type: none"> Company O must hold a Queensland wholesale licence with just the one premises listed on the licence. Company O cannot hold stock at Company L's other premises. 	WL
	<ul style="list-style-type: none"> Company L does not require a substance authority, but both premises must be listed on Company M's wholesale licence, both premises must be listed on Company N's wholesale licence and the one premise must be listed on Company O's wholesale licence. Company L is only authorised to hold stock that Company O sells at the one listed premises. Company L may hold stock that Companies M and N sell at either premise. Company L must keep the stock of each company separate. 	NA
9	Company P is located in Queensland and has contracted Company Q to manufacture a product for them in Queensland. Company Q will send the stock to Company R located interstate who will store the stock and handle the distribution. Company P sells the stock in Queensland and interstate. Company P are also the sponsors of the product with APVMA.	

#	Circumstance/outcome	Substance authority
	<ul style="list-style-type: none"> Company P must hold a Queensland wholesale licence if they do not hold an interstate wholesale licence. 	WL/WL-I
	<ul style="list-style-type: none"> Company Q must hold a Commonwealth manufacturing licence (APVMA). 	ML-C
	<ul style="list-style-type: none"> Company R may be required to hold an interstate wholesale licence. 	WL-I
	<p>Company S is located in Queensland and has a distribution centre. Company S sells their stock to clients from its distribution centre. Company S also holds stock of Company T at their warehouse. Company S receives purchase orders from clients, sends the product to the clients and receives payment from clients on behalf of Company T. At the end of the month, stock is reconciled and money from sales given to Company T, minus a service fee retained by Company S.</p>	
10	<ul style="list-style-type: none"> Company S must hold a Queensland wholesale licence to sell their own stock and the stock of Company T, as they are actually selling their (company T's) stock. Because licences are not typically product specific, and the products are all being sold from the same location, it is likely that only one licence is needed. 	WL
	<ul style="list-style-type: none"> If Company T produces the stock, it must hold manufacturing licence to produce the stock. Any stock provided to Company S to sell must be on a purchase order. 	ML-C
	<ul style="list-style-type: none"> If Company T purchases the stock, it must hold a Queensland wholesaling licence to purchase the stock with the address where the stock is delivered as the premises listed on the licence. Any stock provided to Company S to sell must be on a purchase order. 	WL
	<ul style="list-style-type: none"> If Company T doesn't purchase or produce the stock, and the stock is purchased by Company S, then Company T doesn't need anything as they aren't even involved. 	NA
11	<p>Company U has a distribution centre in south-east Queensland. Companies V, W and X sell stock in Queensland and interstate. Company U holds the stock for the three companies (V, W and X) and Company U's premises are listed as the premises on each company's licence. Company U has opened a new distribution centre in central Queensland to enable faster delivery to customers. Company U has advised the three companies who each wish to use the new centre as a second location.</p>	

#	Circumstance/outcome	Substance authority
	<ul style="list-style-type: none"> Companies V, W and X each have to submit applications to amend their licences to add Company U's central Queensland premises. Alternatively, each company could obtain a new licence for the second premises. Regardless, a fee is payable for the additional premises or licence, each company will need to update their substance management plans accordingly and transfer of stock between the premises must be tracked and recorded. No transfer of stock may occur until the amendments or new licences have been granted. 	WL
	<ul style="list-style-type: none"> Company U does not need a substance authority for the new premises but cannot store stock from a company until the premises has been included on that company's licence. 	NA

ML – Manufacturing licence (Queensland); ML-C – Manufacturing licence/permit etc. (Commonwealth); WL – Wholesale licence (Queensland); WL-I – Wholesale licence (interstate); NA – No Substance Authority

Further information

- For information and application forms for poisons and non-therapeutic use of prohibited substances, please see <https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/poisons>
- For information and application forms for medicines and therapeutic use of prohibited substances, please see <https://www.health.qld.gov.au/system-governance/licences/medicines-poisons/medicines>