Queensland Health

Medicinal cannabis wholesalers, sponsors, and distributors

Medicines and Poisons Act 2019 – Fact sheet – July 2026

Purpose

This fact sheet provides guidance for sponsors and distributors in the context of supplying medicinal cannabis products[1] in Queensland. It covers the roles and responsibilities of the sponsor and distributor, and how an entity may apply for, a wholesale licence (initial or amendment) under Queensland laws, including where a third-party distributor (an entity used by the sponsor to distribute product on its behalf) is to be used, and what actions need to be taken by sponsors and distributors to comply with legislative requirements. For information about Commonwealth medicinal cannabis requirements including sponsors using distributors and information about direct control, see background information below.

Note: Medicinal cannabis is included in Schedules 3, 4 and 8 of the Poisons Standard.[2]

This fact sheet does not introduce any new legislative requirements. It provides information on existing requirements only and does not propose amendments. There have been no recent amendments to Queensland's legislative framework relevant to this fact sheet.

Background

Medicinal cannabis is regulated by both Commonwealth and State/Territory health agencies. In Queensland, the legislative framework that governs dealings with medicines is the *Medicines and Poisons Act 2019* (**MPA**) and the Medicines and Poisons (Medicines) Regulation 2021 (**MPMR**).

For general information on wholesaling medicines in Queensland see: Medicines wholesale.

At a Commonwealth level, the Therapeutic Goods Administration (**TGA**), Office of Drug Control (**ODC**) also regulate medicinal cannabis products.

While this fact sheet refers to many aspects of the Commonwealth framework, Queensland Health does not regulate Commonwealth legislation, and it your responsibility to familiarise yourself with all relevant legislative requirements, including the following publicly available information, in addition to the Therapeutic Goods Act 1989 (Cwth) (**TG Act**) and Narcotic Drugs Act 1967 (Cwth) (**ND Act**):

- Importing, manufacturing and supplying medicinal cannabis in Australia (TGA)
- Medicinal cannabis hub (TGA)
- Medicinal cannabis: Information for sponsors (TGA)
- Medicinal cannabis (ODC)
- Importing medicinal cannabis products into Australia (ODC)

[1] Medicinal cannabis is included in Schedules 3, 4 and 8 of the Poisons Standard.

- Wholesaling vs distribution (TGA)
- Meaning of 'Direct control' (TGA)

How does the scheme regulate medicinal cannabis wholesalers?

Wholesalers of medicinal cannabis, like wholesalers of other medicines, must hold a wholesale licence where stock of the medicinal cannabis is stored in Queensland, or the entity is based in Queensland.

A wholesale licence is a type of substance authority under the Medicines and Poisons Act 2019 (**MPA**) that authorises a person to carry out the following regulated activities with a regulated substance stated in the licence:

a) buying stock of the regulated substance
b) possession of the regulated substance at a place stated in the licence
c) possession of the regulated substance for transportation to a place where a person is authorised, or where it is not unlawful for a person, to possess the substance;
d) supply of the regulated substance, primarily by wholesale, to —
    i. if the licence states a class of persons to whom the substance may be supplied — a person who is a member of the class; or
    ii. otherwise —a person who is authorised, or for whom it is not unlawful, to carry out a regulated activity with the regulated substance;
e) disposal of waste from the regulated substance

Key terms and concepts

Unapproved medicinal cannabis products

Unapproved medicinal cannabis products (or unapproved therapeutic goods) are those products that are not included on the Australian Register of Therapeutic Goods (**ARTG**). For more information on unapproved therapeutic goods and the ARTG, see here:

- Unapproved therapeutic goods
- Australian register of therapeutic goods

Finished medicinal cannabis products

Finished medicinal cannabis products (or finished goods), as opposed to starting materials, are products that are in a form that can be supplied to a patient. See the TGA's website for more information.

Sponsor

As per the TGA guidance, the person or company in Australia who provides a medicinal cannabis product to the treating medical practitioner or pharmacist is considered the 'sponsor' of that product.

The sponsor will be the person or company that:

- imports the medicinal cannabis product/s into Australia;
- manufactures medicinal cannabis products for supply in Australia or elsewhere; or

- arranges for another party to import or manufacture medicinal cannabis products on their behalf.

Read the TGA's guidance on Role of the sponsor for more information.

Distributor

A distributor (or third-party distributor) may be used by a sponsor in distributing a sponsor's products, or to store their products in the distributor's warehouse, in specific circumstances.

Direct control

The TGA requires a sponsor to hold medicinal cannabis products under its 'direct control', which means the sponsor must:

- maintain legal ownership of the product, and
- make decisions as to where and how the products are to be kept, and to whom (i.e. the Authorised Prescriber (AP) or the Special Access Scheme (SAS) approval holder) the products are to be supplied.

Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme

Generally, it is unlawful for a sponsor to supply a therapeutic good that is not included in the ARTG. However, the Commonwealth Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme can authorise specific registered health practitioners to import and/or supply an 'unapproved' therapeutic good for a patient under their direct care.

The sponsor for an unapproved good is responsible for ensuring that an exemption, approval or authorisation under one of the SAS pathways or AP scheme is in place prior to the release of a therapeutic good.

Wholesaler

In Queensland, a wholesale licence granted under the MPA is also required by the sponsor and the distributor, authorising the persons stated in the licence to carry out the regulated activity/s stated in the licence, with a regulated substance permitted under the licence (in this case, medicinal cannabis).

Roles and responsibilities

Sponsor

> The role of the sponsor is to obtain and maintain all necessary licences and approvals at a State and Commonwealth level, including a medicines wholesaling licence from Queensland Health that covers each site where medicines are stored.

The sponsor's role is to make decisions about their medicinal cannabis products that ensure compliance with Queensland's medicines legislation including where and how the product is to be kept and to whom the product can be supplied to.

In addition, it is the sponsor's responsibility to comply with all legislative requirements set out by the TG Act, ND Act, MPA and MPMR, including the Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8 (the Code). Compliance is required to manage

the risks of unlawful supply or access, to ensure any necessary public health alerts and recalls can be managed appropriately, and to maintain direct control.

Direct control

Direct control has specific meaning as stated above in the key terms. TGA requirements do not allow unapproved products to be sold from wholesaler to wholesaler as this would result in loss of direct control by the sponsor.

To maintain direct control of unapproved medicinal cannabis products, the products must be kept in a warehouse under the direct control of the sponsor until they are received by an authorised buyer under one of the TGA approved pathways (e.g. SAS or AP). Refer to the TGA website for further information about these pathways, Importation, manufacture and supply of unapproved medicinal cannabis products | Therapeutic Goods Administration (TGA).

Supplying to authorised persons

The sponsor must receive a compliant purchase order for each transaction and notify the distributor to dispatch the goods on their behalf. Prior to doing so, the sponsor must ensure that all required customer validation processes occur to confirm that the person buying the medicinal cannabis product has the necessary TGA SAS/AP approval.

Security Risk Assessments

Under the Code, wholesalers handling medicinal cannabis need to undertake a Security Risk Assessment of the wholesale business. This must take into account the type and quantities of medicinal cannabis, the premises and their location and the operational aspects of the wholesale business, so as to determine whether their risk profile is high, moderate or low.

For any sponsor of medicinal cannabis using a distributor, given the potential total quantities to be held at the distribution site, Queensland Health determines the level of risk to be at least moderate.

As a result, sponsors should engage the services of a consultant who has registration or licensing in security in at least one State/Territory and appropriate industry knowledge to assist in the preparation of the Security Risk Management Plan (**SRMP**) in compliance with AS/NZS ISO 31000:2009. The SRMP must be reviewed and updated the sponsor to reflect operational changes that result in a significant increase in risk.

Substance Management Plans and Security Risk Management Plans

Under Queensland's MPA, sponsors who are a wholesale licensee, must have their own Substance Management Plan (**SMP**) (Schedule 17, MPMR) and their own SRMP (Section 71, MPMR) for each location that they store medicines, including where a distributor is used. Sponsors using distributors may incorporate a distributor's SMP/SRMP, but each plan must be in the name of, and prepared by, the sponsor.

The SRMP and the security consultant's report should be made available for inspection by Queensland Health inspectors appointed under the MPA.

Loss reporting

A sponsor who is a licensed wholesaler, must report the loss or theft (Section 231, MPMR) of medicinal cannabis that was in the possession of the wholesaler immediately before the loss or theft. This includes where the medicine was in the possession of a carrier delivering the medicine. Wholesalers are responsible for the medicinal cannabis products up until the point of transfer to the authorised buyer. At this time the wholesaler must obtain a signed notice

acknowledging receipt of the delivery of the stock from the buyer of the stock, or from an adult acting on behalf of the buyer at the buyer's street address.

Distributor

> The role of the distributor is to assist the sponsor to distribute their medicinal cannabis product to customers in compliance with all State and Commonwealth requirements.

Third-party distributors can be used as part of the supply chain to assist the sponsor to warehouse and deliver their medicinal cannabis product to customers. To maintain TGA direct control requirements, and meet Queensland's wholesale licensing requirements, third-party distributors are limited to the following:

- **Storing product**

  It is a distributor's responsibility to ensure that a sponsor's medicinal cannabis product is stored in a way that only the approved persons on that sponsor's wholesale licence can access the product. Where a distributor acts for more than one sponsor at any given time, the distributor **must** have processes in place that limit access by the sponsor (and others) to the stock of other entities.

- **Picking, packing and sending product**

  Distributors can only act on the direction of the sponsor to pick, pack and send medicinal cannabis products. The sponsor (not the distributor) must receive a compliant purchase order for each transaction and notify the distributor to dispatch the goods on their behalf. The distributor must also ensure that all required customer validation processes occur as per the contractual arrangement between the distributor and the sponsor. Distributors may use the courier services of a company on the advice/request of the sponsor.

Site requirements

A third-party distributor who is providing a service to the sponsor must ensure their site complies with the wholesale requirements under the MPA and MPMR, including complying with the Code.

As an entity authorised under the sponsor's licence, distributors must have their own SRMP prepared by a consultant who has registration or licensing in security in at least one State/Territory and appropriate industry knowledge to assist in the preparation of the SRMP in compliance with AS/NZS ISO 31000:2009. The SRMP must be reviewed and updated by the sponsor to reflect operational changes that result in a significant increase in risk.

Where medicinal cannabis products from more than one sponsor are kept at the distributor's premises, the medicinal cannabis products and their relevant systems of records including registers, purchase orders and invoices, must be kept and maintained separately from each other.

Sponsors

Each sponsor that uses a distributor's warehouse and services is required to hold a Queensland wholesale licence that names the distributor's storage site on their wholesale

licence and authorises the distributor's employees to carry out the stated regulated activities. Each sponsor using the distributor must have their own SMP and their own SRMP.

Compliance with sponsor's obligations

As persons authorised through a sponsor's wholesale licence, employees of distributors must ensure that they comply with:

- all relevant provisions of the MPA and MPMR;
- all relevant conditions on the sponsors' licences that they are involved with; and
- all' SMPs of each sponsor that they are involved with.

Other obligations

Queensland Health works closely with other regulatory partners such as the TGA, the Commonwealth Office of Drug Control, the Commonwealth Department of Health, as well as Australia Post. Wholesalers of medicinal cannabis must comply with all requirements of Commonwealth legislation, including that:

- unapproved goods, such as medicinal cannabis, may not be supplied from wholesaler to wholesaler – see TGA guidance for more information; and
- medicinal cannabis products cannot be sent via standard post – see Australia Post dangerous goods guide for more information.

Common questions

Below are the answers to some common questions regarding medicinal cannabis wholesaling in Queensland. Please note that the MPA does not include a licence type for a company to distribute on behalf of another entity or enable 'indent' licences (where the responsible entity does not physically take possession of the product); only wholesale licences to supply medicinal cannabis products are available.

Who holds the licence?

In Queensland, the sponsor is the licenced wholesaler in accordance with TGA direct control requirements.

The sponsor holds the wholesale licence and is named on the licence; in addition to employees of the company who are involved in the dealings at the licenced sites.

Where the sponsor uses a distributor for medicinal cannabis, that entity is also named on the sponsor's licence including employees of the distributor.

Is a licence required for interstate sponsors?

Where a sponsor holds a wholesale licence in another jurisdiction, they will not require a Queensland licence as long as they **do not store** stock in Queensland. In this scenario the sponsor must deliver the stock directly from interstate to the buyer, usually a pharmacist or a medical practitioner under the relevant TGA pathway, either the SAS or AP. However, if they contract a distributor to store their stock in Queensland, then the sponsor will require a Queensland wholesale licence. This is in accordance with **Schedule 14, Part 2 of the MPMR.**

What dealings apply to wholesale licences?

A wholesale licence under the MPA/MPMR authorises the holder of the licence to supply the medicinal cannabis products by wholesale. The definition of 'supply' in **s24 of the MPA** is:

> **24 Meaning of *supply* a regulated substance**
> (1) ***Supply***, a regulated substance, means sell or give the substance to a person.
> *Note—*
> See also section 25 in relation to particular ways of selling and giving regulated substances.
>
> (2) However, ***supply***, a regulated substance, does not include—
>
> (a) if the substance is a medicine—administer the substance; or
> (b) if the substance is a poison—apply the substance; or
> (c) dispose of waste from the substance.

This definition is further expanded in **s25 of the MPA**:

> **25 Meaning of particular terms for supply**
> (1) ***Sell***, a regulated substance, includes attempt to sell the substance or make the substance available for sale.
> (2) ***Dispense***, a medicine, means sell the medicine to a person on prescription.
> (3) ***Give a treatment dose***, of a medicine, means give 1 or more doses of the medicine to a person to be taken by a particular person, or administered to an animal, at a later time.

The terms "dispense" and "give a treatment dose" do not apply to a medicine wholesale licence. However, it's important to understand that the licence holder will be "selling" medicinal cannabis products under a wholesale licence.
Importantly, under TGA requirements, medicinal cannabis products cannot be sold from one wholesaler to another. The sponsor must retain legal ownership of the products and is the only entity authorised to supply (i.e., sell) the medicinal cannabis products. For this reason, the sponsor, not the distributor, must hold a licence to sell medicines wholesale.

What can a distributor do?

The distributor, whilst having an agreement with the sponsor to undertake certain activities on behalf of the sponsor, is not the licensed 'wholesaler' of the products. The employees of the distributor can only undertake regulated activities as specified in a sponsor's wholesale licence. Typically this includes being in possession, supplying (but not selling) the product, and disposing of waste. In effect, this means that a distributor is only permitted to:

- store medicinal cannabis products
- pick, pack and send medicinal cannabis products on a sponsor's direction under a lawful purchase order
- dispose of waste from medicinal cannabis products on direction from a Sponsor.

What can't a distributor do?

The distributor does not take on responsibilities for:

i) buying medicinal cannabis products

ii) making decisions on where and to whom the medicinal cannabis product is supplied.

Distributors also cannot move medicinal cannabis products to another wholesaler or distributor, including another licensed location operated by the distributor, for any reason, including for disposal.

What responsibilities does the licensed wholesaler (Sponsor) have?

The sponsor is responsible for making decisions associated with medicinal cannabis dealings and ensuring they have the appropriate Commonwealth and Queensland licences, approvals and permits in place to buy/obtain the medicinal cannabis products and supply the products.

The sponsor must ensure that the medicinal cannabis products are only supplied to persons authorised to buy/possess them, and that the supply of the products meets all Commonwealth and Queensland requirements.

Ultimately, the wholesaler is responsible for ensuring that all requirements of the MPA/MPMR are met and that conditions of the wholesale licence are complied with, including for example:

- reporting loss or potential theft of medicinal cannabis product to the chief executive of Queensland Health (chief executive) and the Queensland Police Service (QPS) under section 226 MPMR Reporting lost or stolen medicine - s226 MPMR;
- maintaining separate records of transactions involving the medicinal cannabis;
- promptly notifying Queensland Health of any changes in circumstances affecting an authority as per the requirement under section 42 of the MPMR. Refer to https://www.health.qld.gov.au/medicines-poisons-forms/s42 that describes the changes that are required to be notified.

Schedule 1 of the MPA defines who is a relevant person, being "a person who is, or is proposed to be, responsible for overseeing or supervising the regulated activity under the authority".

There can be one or more supervisors for a site named in a wholesale licence. Supervisors can be from the sponsor, the distributor or both. The details of the supervisors must be maintained, with any changes notified promptly to Queensland Health using the "Notice of change in circumstances affecting authority form – s42 of the MPMR.

What is required to apply for a wholesale licence?

The entity applying for a wholesale licence (sponsor) should refer to this guide: https://www.health.qld.gov.au/__data/assets/pdf_file/0040/1488937/guide-medicines-wholesale-licence-applicants.pdf for a full list of requirements.

For further information on how to apply for a wholesale licence please go to Wholesaling of medicines | Queensland Health

Who must prepare and maintain a Substance Management Plan?

The sponsor is required to prepare a substance management plan **(SMP)** (Section 93 MPA, Schedule 17 MPMR) in their name as the entity applying for or holding the licence, outlining how known and foreseeable risks associated with their activity at each of the nominated

location/s on the wholesale licence application will be addressed. If using a third-party distributor, the sponsor must ensure, before any dealings occur, that staff of the distributor are aware of, and have a copy of, the SMP.

For further information on SMPs refer to Guide to developing a Substance management plan for medicines: (health.qld.gov.au)

Who must prepare and maintain a Security Risk Management Plan?

Section 71 of the MPMR states that a supplier must comply with and take all reasonable steps to comply with the requirements of the Code. Section 9 of the Code specifically addresses 'Security arrangements and procedures' that wholesalers should consider in terms of managing and implementing security risk strategies such as audits and risk assessments to prevent diversion and unauthorised access to the product.

Accordingly, a wholesaler that deals with medicinal cannabis products is required to have and maintain a **SRMP** for each site nominated on the wholesale licence application.

Distributors, although they are not wholesalers, should also prepare an SRMP relevant to the activities they undertake on behalf of a sponsor.

For more information refer to Sections 9 and 10 of the Code

Can a sponsor use a distributor's Security Risk Management Plan?

No.

As advised above, the sponsor is required to have and maintain an SRMP in their name (as the entity applying for or holding the licence), for each site nominated on the wholesale licence or application.

However, sponsors can, and should, incorporate aspects of a distributor's SRMP into their own SRMP.

Who must notify of changes to the substance authority?

Under **s42 of the MPMR**, the sponsor (the holder of the wholesale licence) is required to notify the chief executive via an approved form (located on the Queensland Health website) of any changes to the nature of the wholesale licence.

Changes may include updating an authorised place, changes to a relevant person stated on the substance authority (such as a supervisor), or any other information that may impact the holder's circumstances to comply with the conditions of the licence.

Whilst the Sponsor **must** notify of any changes, the distributor and employees of the distributor named on the wholesale licence ***may*** also notify the chief executive of any changes affecting operations within the distributor's business, provided that it is clear the notification is being made relevant to the sponsor they are distributing medicinal cannabis product for. For further information please go to Notice of change in circumstances affecting authority (MPMR-42) | Queensland Health

Are there any reporting or notification requirements?

Yes.

The **MPMR Chapter 8, Part 5** requires people dealing with medicines to report certain matters to the chief executive in a range of circumstances (e.g. when the lost or theft of an

S8 medicine is suspected or when prescriptions or purchase orders are suspected to be unlawful e.g. false or fraudulent). These forms can be accessed via Reporting medicines matters to the chief executive | Queensland Health.

It is the responsibility of the sponsor to ensure that these reports are made within the required time. If a distributor completes a notification, it must be clear that the notification is being made relevant to the sponsor they are distributing medicinal cannabis product for. Arrangements for reporting should be detailed in the sponsor's SMP.

Further, the TGA requires sponsors to submit supply records every six (6) months to show what products, and their active ingredients, have been supplied to persons who have AP or SAS approvals. This data helps prescribers determine which product may be suitable for their patient. For more information please go to Sponsor six monthly reporting form | Therapeutic Goods Administration (TGA)

Compliance Inspections

Sponsors and distributors of medicinal cannabis must be aware that regular compliance inspections by Queensland Health inspectors are required as part of the licensing process, and in some cases, distributors may be visited by inspectors from one of Queensland Health's Public Health Units multiple times a year depending on how many sponsors use the services of the distributor.

Further information

Associated guidance documents

- Wholesaling of medicines | Queensland Health
- When is a wholesale licence required by the MPA? | Queensland Health
- Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8 | Therapeutic Goods Administration
- Reporting medicines matters to the chief executive | Queensland Health
- Importation, manufacture and supply of unapproved medicinal cannabis products | Therapeutic Goods Administration
- Sponsor six monthly reporting form | Therapeutic Goods Administration

Contact

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