Medicines and Poisons Act 2019

Fact sheet – current as at July 2023

Medicinal cannabis wholesalers

Regulating medicinal cannabis

The responsibility for regulating medicinal cannabis is shared between the Commonwealth and Australian States and Territories.

In broad terms, the Commonwealth determines what medicines may be manufactured or imported for therapeutic purposes, and individual States and Territories regulate the wholesale supply of such medicines.

All therapeutic goods and products must be approved for use by the Commonwealth (unless compounded for a particular patient) and:

- registered on the Australian Register of Therapeutic Goods (**ARTG**) (a register of therapeutic goods that can be lawfully supplied in Australia); or
- approved by the Therapeutic Goods Administration (**TGA**) for treatment of a particular patient or class of patient.

Some medicinal cannabis products are registered on the ARTG for domestic supply. However, most medicinal cannabis products are unapproved therapeutic goods, and are not registered on the ARTG.

Consequently, a patient's treating doctor must obtain approval from the TGA to access the medicinal cannabis products to be used in a patients' treatment regime (unless a compounded product is prescribed).

In Queensland, any medical practitioner (such as a general practitioner or medical specialist) is able to prescribe medicinal cannabis to a patient they believe will benefit from its use in their treatment, provided they hold a TGA approval for the product (where the product is an unapproved medicine) for that patient.

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

What requirements and conditions apply to the wholesale of medicinal cannabis?

When carrying out a regulated activity under the MPA, all persons including wholesalers, must comply with the requirements for that activity. Chapter 4, part 4 of the Medicines and Poisons (Medicines) Regulation 2021 (**MPMR**) specifies the requirements for supply of medicines. In addition to these requirements, substance authorities, such as wholesale licences, are subject to conditions.

Standard conditions that apply to all substance authorities

Chapter 3, part 6 of the MPMR prescribes several standard conditions that apply to all substance authorities, including wholesale licences.

The standard conditions prescribed are:

- an obligation to keep invoices;
- an obligation to ensure records required to be kept are available for inspection;
- a requirement to notify the chief executive of material changes to details specified in the substance authority; and
- a requirement to notify the chief executive if the holder of the substance authority proposes to stop carrying out an activity under the substance authority.

Changes to standard conditions and/or additional conditions that apply to wholesale licences

In addition to the standard conditions described in chapter 3, part 6 of the MPMR, the chief executive may decide to change the standard conditions and/or impose additional conditions on a particular licence.

If the chief executive decides to grant an application for a wholesale licence which is subject to additional conditions or changes to any standard conditions, or decides to refuse to grant

the application, the chief executive must give the applicant an information notice for the decision.

In the case of a wholesale licence which applies to schedule 3, 4 or 8 medicinal cannabis as a regulated substance, there are some changes to standard conditions or additional conditions that the chief executive may impose.

Any changes to standard conditions or the imposition of additional conditions is decided on a case-by-case base by the chief executive, after careful consideration of an applicant's specific circumstances.

Such conditions may be imposed or changed for numerous reasons, including:

- to mitigate an identified degree of risk associated with selling a particular regulated substance, like schedule 3, 4 or 8 medicinal cannabis or an unapproved medicine;
- to emphasise or clarify the obligations of wholesale licence holders applying in particular circumstances;
- to clarify the interface with Commonwealth legislation;
- to manage expectations of wholesale licence holders; and
- to ensure alignment with the *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8.*

The reasons for changing the standard conditions and/or imposing additional conditions will be stated in the licence documentation.

Compliance with the conditions and requirements of a substance authority is mandatory.

Failure to comply with a standard condition or requirement of the MPMR without a reasonable excuse may attract a significant penalty – see section 71 and Chapter 2 of the MPA.

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.

Associated guidance documents

- When is a wholesale licence required – factsheet
- Wholesale representatives – factsheet
- Wholesale licence – initial application form and guideline

- Wholesale licence – amendment application form
- Wholesale licence – renewal application form
- Fees – factsheet
- Commonwealth manufacturers – fact sheet
- Australian Code of Good Wholesaling Practice for Medicines in Schedule 2, 3, 4 and 8
- Supply and wholesaling of medicinal cannabis products (MCP) (April 2021), Therapeutic Goods Administration Medicinal cannabis: Information for sponsors and manufacturers | Therapeutic Goods Administration (TGA)
- Therapeutic Goods Administration – website: www.tga.gov.au

Further information

For further information, contact the Healthcare Approvals and Regulation Unit:

- Email: HARU@health.qld.gov.au