Australian Government
Department of Health
Therapeutic Goods Administration

# Supply and wholesaling of medicinal cannabis products (MCP)

Version 1.0, April 2021

TGA Health Safety Regulation

## Key Points

If you import or manufacture medicinal cannabis products in a form that can be taken by a patient:

- You must keep the medicinal cannabis product under your **direct control**
- The medicinal cannabis product must only be supplied under an **approved pathway**, being one of:
  - Special Access Scheme B (SAS B)
  - the Authorised Prescriber scheme (AP), or
  - for an approved or notified clinical trial, and
- You **must not supply** the medicinal cannabis product **by wholesale**, including to wholesalers licensed under state or territory law.

## Summary

Wholesale supply of any finished therapeutic goods that are not included in the Australian Register of Therapeutic Goods (**the Register**), including medicinal cannabis products (**MCP**), is not consistent with the therapeutic goods regulatory framework.

A person who supplies unregistered MCP by wholesale is likely to contravene the *Therapeutic Goods Act 1989* (**TG Act**). Those contraventions may result in regulatory action under the TG Act, and can also have implications for licences issued under the *Narcotic Drugs Act 1967* (**ND Act**), *Customs (Prohibited Imports) Regulations 1956* (**CPI Regulations**) and state and territory legislation.

The legal requirements that apply when supplying MCP depend on whether the supplier is the 'sponsor' of the goods. Both sponsors and persons who are not the sponsor are prohibited from supplying unregistered MCP by wholesale.

## Who is the sponsor of the goods?

The term sponsor is defined in the TG Act. The definition is activities based, meaning that whether a person is a sponsor of particular goods will depend on whether they are engaged in particular activities relating to those goods.

In summary, a person will be the sponsor if the person is a resident of, or carrying on business in, Australia, and is responsible for bringing therapeutic goods into the domestic market (by importing or manufacturing them) or exporting goods from Australia. Where the sponsor supplies therapeutic goods to another person the 'sponsorship' does not transfer to that person, unless the purchaser is responsible for exporting the goods from Australia.

### Import, export, manufacture or supply of unregistered MCP by a sponsor prohibited unless subject to exemption, authority or approval[1]

The TG Act provides that a person who is the sponsor of therapeutic goods must not import, export, manufacture or supply those goods unless the goods are:

a. entered on the Register as listed or registered goods in relation to that person

b. exempt goods

c. exempt under section 18A

d. the subject of an approval or authority under section 19, or

e. the subject of an approval under section 19A.[2]

## Starting materials for use in manufacturing MCP

Starting materials for use in manufacturing therapeutic goods are exempt goods, unless they are pre-packaged for supply for other therapeutic purposes or are formulated as a dosage form.[3] This means that the TG Act allows the importation, manufacture, supply or exportation of starting materials (including active pharmaceutical ingredients) unless they are in a form that can be given to a patient.

MCP in a form that can be supplied to a patient (that is, 'finished' MCP), it is not subject to this exemption. To import, manufacture, supply or export such goods, they must either be registered or listed, or subject to an exemption, approval or authority. The import into or export from Australia of MCP as starting material or finished goods must comply with the requirements set out in the ND Act and the CPI Regulations.

## Importing and manufacturing finished MCP

There are exemptions that allow the importation or manufacture of finished MCP that are not registered in the Register by sponsors, subject to certain conditions.[4]

Those exemptions require that MC products imported into Australia with an appropriate licence and approvals, or manufactured in Australia under a licence issued under Part 3-3 of the TG Act, be:

a. held under the **direct control** of the sponsor (importer or manufacturer)

b. kept in a warehouse or a properly secured area under the control of the sponsor, and

c. supplied in accordance with a relevant notification, approval or authorisation (see below).

The sponsor is also required to keep records relating to the source and supply of the goods, and give those records to the TGA on request.

[1] This fact sheet does not discuss other possible exemptions from Part 3-3 of the TG Act such as those at item 6 of Schedule 5 or item 5 of Schedule 5A to the *Therapeutic Goods Regulations 1990* (Cth).
[2] *Therapeutic Goods Act 1989* (Cth), sections 19B and 19D.
[3] *Therapeutic Goods Regulations 1990* (Cth), Schedule 5, Item 9.
[4] *Therapeutic Goods Regulations 1990* (Cth), Schedule 5A, Items 1 and 2.

If the MCP are not held under the direct control of the sponsor, or the above conditions are not complied with, the exemption will not apply, and the importation or manufacture of those goods will be unlawful.[5]

## Loss of 'direct control' through a distribution agreement

If a contract transfers legal ownership of the MCP to a person other than the sponsor, or results in the sponsor no longer having control over or knowledge of how the goods are stored, where the goods are located, and when the goods are used, it is unlikely that the sponsor (importer or manufacturer in Australia) could be said to have the goods under its direct control.

Similarly, if the sponsor and the distributor have a contract where the sponsor (importer or manufacturer in Australia) maintains legal ownership of the MCP, but as a practical matter act inconsistently with that contract (for example, because the sponsor rarely knows where the MCP are stored, or the MCP are supplied without the sponsor's knowledge or direction), it is unlikely that the direct control exemption will apply.

If the sponsor no longer has direct control over the MCP, or fails to comply with the conditions of the exemption, the exemption will not apply and the importation or manufacture of the goods will have been unlawful, as will the supply of the goods.[6]

Examples of where the MCP may no longer be held under the direct control of the sponsor include where the MCP are supplied to someone other than an authorised medical practitioner or pharmacist, or the ultimate consumer of the goods. This is the case even if the goods are being supplied to a wholesaler licensed by a state or territory government.

Whether someone other than the sponsor taking custody of the goods results in the goods no longer being under the 'direct control' of the sponsor will depend on the circumstances. At a very high level, a distinction can be drawn between:

a. 'wholesale' arrangements, where the goods are sold to a third party and the sponsor relinquishes control over the goods (thereby, no longer having direct control over the goods), and

b. 'distribution' arrangements, where the third party provides services to the sponsor (such as warehousing, courier and brokering services) in relation to the goods, but the sponsor retains ownership of and direct control over the goods at all times before they are supplied.

## Maintaining 'Direct Control' with distribution agreement in place

For a sponsor to be said to maintain 'direct control' over MCP, and for the other conditions for the Direct Control Exemptions to be met in relation to MCP, we consider that any distribution contract should (generally) provide for the MCP Goods to:

a. remain the sponsor's property until they are supplied as approved or authorised under SAS B, AP or the clinical trial exemption;

[5] *Therapeutic Goods Act 1989* (Cth), sections 19B and 19D.
[6] *Therapeutic Goods Regulations 1990* (Cth), regulation 12; *Therapeutic Goods Act 1989* (Cth), sections 19B and 19D.

b. be kept in a warehouse or secured area which is known to the sponsor, and over which the sponsor has contractual and practical control; and

c. only be released for supply with approval from the sponsor (with any supply or movement of the goods being specifically notified to the sponsor, so that the sponsor maintains appropriate records as required by the conditions).

Sponsors or persons who operate under a distribution agreement relating to finished MCP not on the Register are reminded that apart from compliance with the TG Act, they must also comply with all State or Territory laws and reporting obligations relating to the storage and supply of prescription only medicines or controlled drugs.

## Supply of finished MCP by a sponsor

In order for a sponsor to comply with the requirements of the exemption, finished MCP that has been imported or manufactured under the exemption must only be supplied under one of the following approved alternative pathways:

a. the authorised prescriber scheme (**AP**)[7]

b. the Special Access Scheme B (**SAS B**)[8]

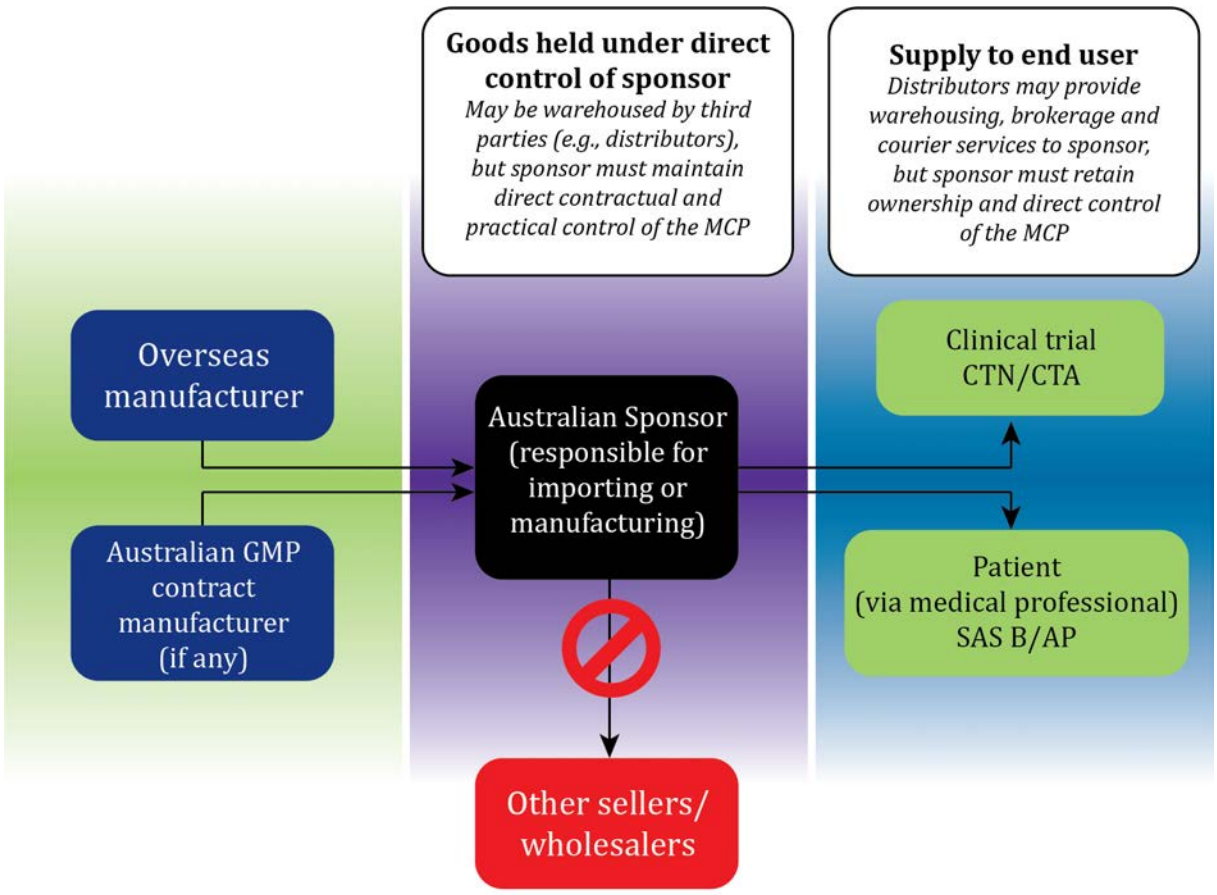
c. a clinical trial notification (**CTN**),[9] or

d. a clinical trial approval (**CTA**).[10]

## Supply of finished MCP by persons other than the sponsor

The TG Act provides that it is a criminal offence for a person who is not a sponsor of a therapeutic good to supply that therapeutic good to '*another person who is not the ultimate consumer of the goods*' (including by wholesale) unless the goods are subject to a relevant exemption, approval or authority. In the case of MCP, this will generally be SAS B, AP, CTN or CTA, as discussed above.[11]

[7] *Therapeutic Goods Act 1989* (Cth), Subsection 19(5).
[8] *Therapeutic Goods Act 1989* (Cth), Paragraph 19(1)(a).
[9] *Therapeutic Goods Regulations 1990* (Cth), Schedule 5A, Item 3.
[10] *Therapeutic Goods Act 1989* (Cth), Subsection 19(1).
[11] *Therapeutic Goods Act 1989* (Cth), section 21.


Goods held under direct control of sponsor
May be warehoused by third parties (e.g., distributors), but sponsor must maintain direct contractual and practical control of the MCP
Supply to end user
Distributors may provide warehousing, brokerage and courier services to sponsor, but sponsor must retain ownership and direct control of the MCP
Overseas manufacturer
Australian GMP contract manufacturer (if any)
Australian Sponsor (responsible for importing or manufacturing)
Clinical trial CTN/CTA
Patient (via medical professional) SAS B/AP
Other sellers/ wholesalers