



Australian Government

Department of Health

Office of Drug Control

Guidance Note – Sponsored Import and Supply of Unregistered Medicinal Cannabis Products – Customs (Prohibited Imports) Regulations 1956

Medicinal Cannabis products are regulated as medicines in Australia. Generally, medicines imported and supplied in Australia must be entered into the Australian Register of Therapeutic Goods (ARTG). However, the *Therapeutic Goods Act 1989* (the TG Act) provides several mechanisms to allow for use of unregistered medicines in certain circumstances.

Under Regulation 5 of the Customs (Prohibited Imports) Regulations 1956 (the PI Regulations) all forms of cannabis, cannabis resins, extracts (including extracts from hemp) and cannabinoids require a licence and permit to import. Imports are restricted to medicinal or scientific research purposes and quantities imported, and supply routes, are strictly controlled, as required under the international drug conventions.

The Australian Government has considered the supply options for medicinal cannabis products and has decided to expand importation of medicinal cannabis products until such time as the domestic medicinal cannabis industry becomes established. Importers may apply for a licence and permit to import, in accordance with Regulations 5 of the PI Regulations, for an importer to supply medicinal cannabis products, subject for the following purposes:

- the Special Access Scheme
- Authorised Prescriber
- Clinical Trials

Importers should note that imported medicinal cannabis products are subject to a [Therapeutic Goods Order](#) and may also be required to be manufactured overseas in accordance with appropriate manufacturing standards. For further information contact the [Therapeutic Goods Administration](#) (TGA) www.tga.gov.au.

Import requirements

As per standard import requirements, the importer must establish that they are permitted to supply medicinal cannabis products within their state/territory. As prescription only controlled drugs, the importer must provide the relevant licences/approvals to possess/supply the drugs to be imported at the time of the licence application. Refer to [our guidelines on narcotic imports](#) for more information (<https://www.odc.gov.au/importers#narcotic>)

The importer must provide information with their licence application on quantities to be imported and the grounds for which the demand for the medicinal cannabis product has been determined.

Importers should ensure before making an import application that the exporter has appropriate licence/approval from the overseas federal level government to request for export approval of medicinal cannabis products to Australia.

In addition to standard conditions of import, as prescribed on the import permission and regulations, importers utilising this process may be subject to the following conditions, as appropriate:

The importer shall:

1. Only supply medicinal cannabis products imported under this import permission for patient use when supply is authorised under any of the following provisions of the *Therapeutic Goods Act 1989* (the TG Act).
 - a) Special Access Scheme – Category B approval (SAS Category-B approval); Paragraph 19 of the TG Act.);
 - b) Section 19(5) of the TG Act also known as Authorised Prescriber scheme; or
 - c) Section 18(1) clinical trial notification scheme (CTN) or Section 19(1)(b) of the TG Act approval for use solely in a clinical trial (CTX).
2. Keep the imported products in a secure warehouse or other properly secure area, in accordance with State or Territory requirements for the storage of schedule 8 or schedule 4 drugs (whichever is applicable) as defined in the *Schedule for the Uniform Scheduling of Medicines and Poisons* (SUSMP).
3. In relation to supply under the Special Access Scheme, the importer must obtain a copy of the SAS Category B approval and must not supply in excess of the treatment protocol and expiry date of the approval.
4. In relation to supply to an Authorised Prescriber, the importer must obtain a copy of the prescribers' authorisation under subsection 19(5) of the TG Act and must only supply in accordance with the product listed on the authorisation.
5. Keep records of supply of the imported products as described above and provide reports on request and a quarterly basis in a format provided by the Office of Drug Control. Records must include date of supply, Persons/Company whom have been supplied the goods, authority of the supply (outlined in condition 1), quantities supplied, stock levels, and records of destruction of stock, losses or thefts.

Further information can be found on our website www.odc.gov.au or by contacting us via email at dc@health.gov.au

Office of Drug Control
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