Australian Government
Department of Health
Office of Drug Control

Medicinal Cannabis Cultivation and Production Licences – Testing of Cannabis and Cannabis Resin

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1. Purpose

This policy has been developed to provide advice on what is allowable in the testing of cannabis and cannabis resin by licence holders under the *Narcotic Drugs Act 1967* (the Act), where those licences allow for the cultivation and production of medicinal cannabis.

These licences are collectively known as cannabis licences and the activities authorised under such licences are outlined in general terms under sections 8E and 9D of the Act. Both sections of the Act list a number of related activities ancillary to the primary activities of obtaining, cultivation or production, but noting that the related activities are not limited to those on the list. The *Narcotic Drugs Regulation 2016* further provides an example (s.5(2)(f)) of such related activities to 'include, for example, testing cannabis to determine the concentration of tetrahydrocannabinol in the leaves and flowering heads of cannabis plants'.

2. Policy on testing

Cannabis licences issued under the Act are conditioned with a range of additional requirements and authorisations and exclusively, to date, have included 'testing' as part of the related authorised activities. What has been somewhat concerning for licence holders has been defining the parameters of that testing – that is, what can and cannot be done in testing.

The Office of Drug Control policy position is that testing by a laboratory conducted on behalf of a cannabis licence holder is an authorised activity under the Act and does not require the laboratory to hold a separate manufacture licence.

2.1 Manufacture or testing

One of the concerns in defining such parameters has been that in some forms of testing the nature of the cannabis or cannabis resin is changed such that the precursor to the testing is actually creating a drug. Creating a drug indicates that a manufacture process has occurred as defined under the *Single Convention on Narcotic Drugs 1961* ''Manufacture' means all processes, other than production, by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs'.

To conduct manufacturing activities for medicinal cannabis generally requires a separate licence to do so under the Act. Such a requirement would, however, be an overly burdensome regulatory requirement where the purpose of such process is *only for the assay* of material cultivated and produced under a cannabis licence. In other words, in small amounts and where the end use is consumption through testing.

2.2 Testing for what?

Under cannabis licences and permits, licence holders are required to demonstrate the range of cannabinoid content of cannabis or cannabis resin produced for supply or for research purposes. Generally speaking (although not exclusively), this means ensuring that cannabis produced under licence has cannabidiol and tetrahydrocannabinol (THC) contents in a range specified in a permit issued by the Office of Drug Control.

In some other cases, and where the eventual manufacture of a drug calls for such, other cannabinoids and/ or terpenes might also be the subject of such assay.

In addition, manufacturers of medicinal cannabis products are required to conform with the quality requirements outlined in *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)* (the Order). This Order is a standard that specifies minimum quality requirements for medicinal cannabis products. Because medicinal cannabis products are of a range of forms and types, the quality requirements under the Order are applied at the herbal or plant stage of the medicine production process.

This means that some manufacturers may require cannabis licence holders to test cannabis or cannabis resin for conformance with the Order. The types of things that might be tested under the Order include the presence of heavy metals, aflatoxins, pesticides etc.

2.3 The role of laboratories

Laboratories likely to be involved in the testing of cannabis are generally involved in a range of assay and/or other testing processes. The testing of cannabis and cannabis extracts is just one of the activities in the operation of such laboratories.

To reduce the regulatory burden of requiring laboratories to obtain a manufacture licence under the Act, the following is laid out as policy:

- Cannabis or cannabis resin extracted by the licence holder and supplied to the laboratory is only for testing purposes and not for supply to any other person.
- Cannabis or cannabis resin supplied must be tracked and amounts supplied, consumed and destroyed reported by the cannabis licence holder.
- The cannabis licence holder is responsible for any cannabis supplied. That cannabis is considered to be still in the licence holder's possession and control.
- Cannabis or cannabis resin may only be supplied to the laboratory for analysis by a licensed hemp grower, a person licensed under the *Narcotic Drugs Act 1967*, a person licensed to import under Regulation 5 of the *Customs (Prohibited Imports) Regulations 1956*, or person otherwise authorised under State or Territory Law.

Policy specific to cannabis and cannabis products containing THC:

- If the cannabis material contains greater the 0.1% THC, no more than 200 grams may be held by the laboratory at any given time. Any cannabis remaining after testing must be appropriately destroyed or returned to the cannabis licence holder.
- If the cannabis material contains greater than 0.1% THC the Laboratory must hold, if applicable in the relevant state or territory, a Schedule 9 licence (or equivalent) from the state or territory Health Department.
- Laboratories who intend to perform services related to cannabis material of greater than 0.1% THC that do not meet point 1 or 2 above must apply for a licence to manufacture under the Act.

3. Further information

Further information can be found by following the below links:

- Office of Drug Control
  https://www.odc.gov.au/
- Narcotic Drugs Act 1967
  https://www.legislation.gov.au/Details/C2016C01132
- Narcotic Drugs Regulation 2016
  https://www.legislation.gov.au/Details/F2016C01047
- Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)
  https://www.legislation.gov.au/Details/F2017L00286
- Conforming with TGO 93 (Standard for Medicinal Cannabis)
  https://www.tga.gov.au/conforming-tgo-93-standard-medicinal-cannabis