NORTHERN TERRITORY GOVERNMENT

DEPARTMENT OF HEALTH

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Access to Medicinal Cannabis/CBD Oil in the NT Information Sheet

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The term medicinal cannabis refers to 'approved' pharmaceutical products containing cannabis and not the smoking of the raw plant. Medicinal cannabis products include a range of preparations packaged and labelled for human therapeutic use including flowers, liquids, lozenges, oils, sprays, tablets, tinctures, sprays and other extracts.

The authorised therapeutic use of medicines containing cannabis is often confused with the potential legalisation of the raw product (cannabis plant). Cannabis grown for medicinal purposes is under the control of the Australian Government under international treaty. The products are produced by licensed companies that are issued with a permit and are strictly controlled. Medicinal cannabis products may be imported if a suitable product is not available in Australia. This process is controlled by the Australian Government, please refer below for further information.

States and territories determine the criminal and civil penalties related to the use, possession, cultivation or trafficking of cannabis within their jurisdiction and there are a number of Federal offences related to cannabis as well. In the Northern Territory (NT), the growing and use of the cannabis plant and all parts of the plant is illegal under the *NT Misuse of Drugs Act 1990* which is the responsibility of the NT Department of the Attorney-General and Justice.

The exceptions to this legislation are:

- A food product which meets the criteria in the Australia New Zealand Food Standards Code Standard 1.4.4. *Note: food plants and products including seeds must be low THC (under 1%)*
- In the near future, hemp products meeting the criteria of the NT hemp industry legislation. *Note: hemp plants and products must be low THC (under 1%)*
- A cultivator or manufacturer issued with a permit to produce cannabis for human therapeutic use by the Australian Government's Office of Drug Control. For a business based in the NT, a manufacturer/wholesaler licence will need to be issued by the NT Medicines and Poisons Control.
- The product is a pharmaceutical approved or given exemption by the Australian Government's Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1989*, the prescriber has been approved by the TGA to prescribe the product, and the product has been legally supplied by a pharmacy, prescriber or hospital.

Prescribing of medicinal cannabis in the NT

There have only been a small number of well-designed clinical studies on medicinal cannabis treating specific conditions. Due to this it has been difficult for General Practitioners (GPs) to find quality evidence to support a decision to prescribe medicinal cannabis. The TGA hosts such information. It is recommended that patients with medical conditions where medicinal cannabis may be of benefit are referred by a GP to an appropriate specialist for assessment. Please note many of the specialists with expertise in the use of medicinal cannabis are based outside the NT, as are associated clinical trials.

Under NT medicines and poisons law, Schedule 8 (S8) (Controlled drug) medicinal cannabis products are regulated in the same way as other S8 medicines such as morphine and oxycodone. The prescriber does not need to obtain an NT authorisation prior to prescribing a medicinal cannabis pharmaceutical for a particular patient, although 'notification' to the Chief Health Officer is required if treatment is successful and the patient will be receiving the medicine for more than two months. S8 prescriptions must be written by a NT based prescriber (based on a practice address on the prescription) to be dispensed in the NT.

In the NT cannabidiol (CBD) products are Schedule 4 (S4) (prescription only), the same as medicines used for medical conditions such as high blood pressure, diabetes, epilepsy etc. The prescriber does not need an NT authorisation or to notify that they have prescribed an S4 CBD medicine.

As most medicinal cannabis pharmaceuticals are not yet assessed for safety and effectiveness and therefore not registered for the Australian market by the TGA, GPs wishing to prescribe medicinal cannabis must obtain prior approval from the TGA to prescribe an unregistered product.

Pathways available to prescribers include:

- Special Access Scheme (SAS) Category A and B – used for individual patient approvals
- Authorised Prescriber Scheme– a broad approval, so the prescriber needs to demonstrate clinical expertise in the use of medicinal cannabis, which is difficult for NT based prescribers to do as the clinical trials are interstate.

Both application pathways require strong evidence of the medicine's effectiveness compared with alternative safe and readily available medicines.

Conditions for which medicinal cannabis may be prescribed are listed on the TGA website:
https://www.tga.gov.au/access-medicinal-cannabis-products-1

The TGA website also contains educational materials to help prescribers decide whether a medicinal cannabis product is appropriate for a particular patient, as well as information on how to use the available access schemes.

The TGA, NT Chief Health Officer, and NT Department of Health **do not release** lists of authorised prescribers of medicinal cannabis products.

Contact details for enquiries:
https://www.tga.gov.au/form/authorised-prescribers
Email: authorised.prescribers@health.gov.au
Phone: +61 2 6232 8911 (general application enquiries)
Phone: +61 2 6232 8866 (medicinal cannabis application enquiries)
Fax: +61 2 6232 8112

Obtaining medicinal cannabis pharmaceuticals from a pharmacy
Firstly, a prescription is required and it must comply with NT medicines and poisons law.

Medicinal cannabis pharmaceuticals are not routinely stocked by medicines wholesalers or pharmacies, so the dispensing pharmacy needs to order the product especially for the patient from the product sponsor (interstate).

In addition, medicinal cannabis is not subsidised under the Pharmaceutical Benefits Scheme (PBS), so patients must pay the full price of each prescription. Please discuss price with the pharmacy before the medicine is ordered. You may need to pay a deposit.

Please note: S8 medicines can only be dispensed in the NT if the prescriber is also in the NT. Prescriptions written for S8 medicinal cannabis products by GPs based interstate must be dispensed interstate before being sent to the NT.

Patients may bring medicines prescribed and dispensed interstate into the NT for personal use in the manner intended by the prescriber. The medicines must remain in the original packaging and the dispensing label (listing product name, dosage, patients name, prescriber name, pharmacy/dispensing point contact details) must remain on the medicine. It may help to have a copy of the TGA approval document to provide to other health practitioners and the Police if required.

Please contact your GP to discuss the above information.

Further information is available via:
https://www.tga.gov.au/form/authorised-prescribers
https://www.tga.gov.au/access-medicinal-cannabis-products-1
https://www.tga.gov.au/access-medicinal-cannabis-products-steps-using-access-schemes
https://www.tga.gov.au/obtaining-approval-human-research-ethics-committee-or-endorsement-specialist-college
https://www.tga.gov.au/behind-news/claims-about-hemp-and-cbd-oils-misleading-consumers
http://www.tga.gov.au/contact-tga
http://www.tga.gov.au/form/authorised-prescribers#contacts
https://www.tga.gov.au/australian-register-therapeutic-goods
https://www.odc.gov.au/
https://health.nt.gov.au/professionals/environmental-health/medicines-and-poisons-control2/medicines-and-poisons-control
https://www.foodstandards.gov.au/about
https://dpir.nt.gov.au/primary-industry/agricultural-developments/hemp-industry-bill-2019

Links to legislation:

The ***NT Misuse of Drugs Act*** is the responsibility of the NT Department of the Attorney-General and Justice.
https://legislation.nt.gov.au/en/Legislation/MISUSE-OF-DRUGS-ACT-1990

The ***Narcotic Drugs Act*** regulates medicinal use of cannabis and is the responsibility of the Commonwealth Government's Department of Health, Office of Drug Control.
https://www.legislation.gov.au/Details/C2016C01132

The ***Therapeutic Goods Act*** regulates medicines and other therapeutic products for human use and is the responsibility of the Commonwealth Government's Department of Health, Therapeutic Goods Administration.

https://www.tga.gov.au/legislation-legislative-instruments

The ***Hemp Industry legislation*** is the responsibility of the NT Department of Primary Industry and Resources. https://dpir.nt.gov.au/primary-industry/agricultural-developments/hemp-industry-bill-2019

The ***NT Medicines, Poisons and Therapeutic Goods Act*** is the responsibility of the NT Department of Health.
https://legislation.nt.gov.au/en/Legislation/MEDICINES-POISONS-AND-THERAPEUTIC-GOODS-ACT-2012