

MINISTER FOR HEALTH

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Senator Rachel Siewert Committee Chair Standing Committee on Community Affairs PO Box 6100 Parliament House CANBERRA ACT 2600

Via email: Community.affairs.sen@aph.gov.au

Dear Senator

Thank you for your correspondence of 21 November 2019, to the Hon Michael Gunner MLA, Chief Minister of the Northern Territory (NT) advising that the Inquiry into the current barriers to patient access to medicinal cannabis in Australia is open for submissions. Your correspondence has been forwarded to me for response. Please consider this letter as the NT submission to the inquiry.

The authorised therapeutic use of medicines containing cannabis is often confused with the request for the legalisation of the use of the raw product (cannabis plant). States and territories determine the criminal and civil penalties related to the use, possession, cultivation or trafficking of cannabis within their jurisdiction. There are also a number of Commonwealth offences related to cannabis. In the NT, the growing and use of the cannabis plant is illegal under the *NT Misuse of Drugs Act 1990*.

Legislative changes in November 2016 allowed medicinal cannabis therapeutic products to be prescribed in Australia and in the NT. However there have only been a limited number of well-designed clinical studies on medicinal cannabis resulting in limited research evidence to support decisions to prescribe medicinal cannabis. Clinical trials are driven by research gaps and in the future there may be opportunities for the NT to partner with health services in other jurisdictions to participate in clinical trials.

The Special Access Scheme (SAS) Category A and B and the Authorised Prescriber Scheme are exemption pathways used by the Therapeutic Goods Administration (TGA) to allow doctors to prescribe an unregistered medicine; that is, a medicine that has not been assessed for safety or effectiveness. In special circumstances, a patient living in the NT could access a therapeutic agent containing cannabis under one of these schemes as follows:

- An NT medical practitioner who has demonstrated clinical expertise needs to obtain registration from TGA to become an Authorised Prescriber; or
- An NT medical practitioner could apply for individual patient approval under SAS Category A or B



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Each of the above application pathways are based on the premise that there is strong evidence of the medicine's efficacy compared with alternative safe and readily available medicines. Once submitted, the TGA considers the application and decides whether to approve it. The pharmacy dispensing this therapeutic agent would then need to order it for that patient. Prescribers who have obtained authority from the TGA and are treating a patient with a medicine in the controlled drug category (Schedule 8) for two months or more must also comply with the 'Notification' requirement to the NT Chief Health Officer (CHO). There is no requirement at NT level for authorisation or notification for cannabidiol products.

The NT Medicines Poisons and Therapeutic Goods Act 2012 contains provisions to automatically adopt the Commonwealth's Poisons Standard for the scheduling of all medicines and chemicals, thus allowing medicinal cannabis to be prescribed in the NT. A TGA's Authorised Prescriber requires no additional authorisation to prescribe medicinal cannabis in the NT.

Uptake has been slow within the NT with only one prescription dispensed for a Schedule 8 medicinal cannabis product since the change in legislation. The NT Department of Health is aware of a number of other NT residents accessing medicinal cannabis products via interstate specialists. These prescriptions must be supplied from the state of origin. The NT Department of Health does not intervene in the clinical decision making between private GPs and patients. Patients may advocate to their private GP to be an authorised prescriber.

Anecdotal evidence suggests a number of factors may be the cause of the low uptake in the NT including:

- Cost can be prohibitive with no medicinal cannabis products subsidised through the Pharmaceutical Benefits Scheme a six to eight week course can cost over \$750
- There are very few well designed clinical trials using medicinal cannabis resulting in limited evidence for its use in successfully treating different medical conditions, or on effective forms and dosages
- There is a lack of registered medical practitioners in the NT able to prescribe/recommend medical cannabis product and
- The apparent ease of access of illegal raw cannabis

Since 2017, the NT CHO has:

- Provided the Health Providers Alliance NT with information and education sessions regarding Access to Therapeutic Medicines Containing Cannabis in the NT
- Spoken to participants at a professional development meeting which included general practitioners
- Conducted Grand Rounds at Royal Darwin Hospital on the Current Status of Access to Therapeutic Medicines Containing Cannabis in the NT, and
- Provided briefings and sessions to the NT Primary Health Network

Thank you for the opportunity to provide comment on this Inquiry. If you have any questions, please do not hesitate to contact the Ms Leith Wood, Office of the Chief Health Officer

Yours sincerely

NATASHA FYLES

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