Draft guidance on prescribing medicinal cannabis for patients with substance-use disorder is being drawn up by Cannabis Clinicians Australia (CCA) in a move to provide clarity on what has become an issue of contention between prescribers and regulators.

Led by addiction specialist Professor Nicholas Lintzeris from the University of Sydney, the paper contains a “summary of recommendations” when prescribing THC for patients with dependency issues.


Professor Nicholas Lintzeris

It is estimated that 10% to 20% of patients prescribed THC meet the criteria for cannabis dependence, which includes features such as tolerance and withdrawal, cravings, health or social harms and difficulties controlling or reducing use of cannabis.

The issue has taken centre stage in recent weeks following a crackdown by the Pharmaceutical Services Unit (PSU) in New South Wales.

Investigators have questioned dozens of doctors about their prescribing practices, particularly when prescribing THC for patients with substance-use disorders.

The situation has been clouded by the apparent absence of any guidance for prescribing THC for patients with cannabis or other substance-use disorders. Doctors who spoke to *Cannabiz* questioned why the PSU had taken it upon itself to make what appeared to be arbitrary decisions on what should or shouldn’t be prescribed.

It has also led to fears that legitimate prescribing - and reputable and conscientious prescribers - are being unfairly punished.

It is hoped the consensus guidance drawn up by Lintzeris - and put together in collaboration with CCA and the Australian Medicinal Cannabis Association (AMCA) - will provide a degree of clarity for clinicians, patients and regulators over what constitutes sound diagnoses and treatment programs for patients with substance-use disorders.

Lintzeris said the guidance is consistent with general approaches for prescribing other drugs of dependence, such as opioids and benzodiazepines, and aims to minimise safety concerns for patients and the community.

The draft, a copy of which was provided to *Cannabiz*, is currently being reviewed by CCA, the Australian Cannabis Nurses Association (ACNA) and the Australia Cannabis Pharmacy Association (ACPA) before formal sign off by the AMCA board. No major revisions are expected.

It will then be distributed for wider consultation with the industry.

Among the dosage recommendations set out in the guidance, "daily doses of up to 80mg oral or 500mg THC-inhaled medicine may be required for patients with significant tolerance to cannabis".

"It is recommended to seek a second opinion from an experienced medicinal cannabis prescriber for higher doses," it states.

Prescribers are also advised to encourage the use of oral routes of administration for patients who regularly consume THC.

"Inhaled routes… are more likely associated with increased risk of cannabis-use disorder (CUD), although inhaled routes may be preferred for episodic use," the guidance says.

It remains unclear whether adding CBD to THC alters the potential for CUD, it adds.

On dispensing, practitioners are told to consider weekly or fortnightly supplies for patients experiencing difficulties managing their medication and who may run out early.

A summary of the draft recommendations is provided below.

1. Assessment

1.1. History of presenting condition, including current and prior treatment approaches, and where relevant, liaise with other healthcare providers.

1.2. History of cannabis and other substance use.

- Quantity, frequency and type of cannabis used, duration of use, and estimate proportion of cannabis use that is for medical versus non-medical purposes.
- Does the patient meet criteria for a cannabis use disorder (CUD) (specifically mod-severe CUD in DSM5 or dependence in ICD-11)? (Use DSM5 or ICD-11 checklists).
- Does the patient have risk factors for developing CUD with medicinal cannabis? (e.g. inhaled v oral route of administration; poor psychological health; using higher doses of THC, using on daily basis and long-term treatment (more than three months); frequent non-medical cannabis use; male, below age 40; history of other SUDs).

1.3. Examination and investigations

- Consider role of urine drug screens for cannabis or other substance use.
- Examine Safescript for history of MCS8 and other S8/S4D medication use.

2. Patient education and informed consent

2.1. Discuss risks of cannabis dependence and cannabis withdrawal arising from long-term use of MCS8, including factors that increase these risks (daily use, prolonged use of more than several months, inhaled routes, higher THC doses).

2.2. Informed consent to treatment.

2.3. Consider written patient agreement identifying conditions of treatment (e.g. dose escalations, replacing scripts, conditions for stopping MCS8 treatment, Safescript).

3. Tailor treatment according to risk

3.1. Obtain S8 permits as required by local jurisdiction health department, and follow conditions of permit/authority.

3.2. Prescribing guidance

- THC/CBD ratios: unclear as to whether adding CBD to THC alters potential for CUD
- Formulation: inhaled routes of administration more likely associated with increased risk of CUD, although inhaled routes may be preferred for episodic use. Encourage use of oral routes for patients with regular THC use.
- Doses: patients with tolerance to cannabis usually require higher doses of THC, titrated upwards to achieve clinical effect. For individuals with tolerance to cannabis, daily doses of 80mg oral or 500mg THC inhaled may be required. It is recommended to seek a second opinion from an experienced medicinal cannabis prescriber for higher doses.

3.3. Dispensing

- Consider interval dispensing (e.g. weekly/fortnightly supplies) for patients experiencing difficulties managing their medication (e.g. running out early).
- Discuss safe storage of medications.
- Discuss potential for drug-drug interactions, including alcohol and sedating medications.

4. Monitoring and clinical documentation

4.1. Regularly monitor and document effectiveness of medicinal cannabis in treating the primary condition – including symptom reduction and functional outcomes. Consider discontinuation of MCS8 treatment if no clinically significant improvement over time.

4.2. Regularly monitor safety (adverse events, DDIs).

4.3. Regularly monitor medication adherence, including regular examination of Safescript for evidence of the patient's S8 and S4D medication use. Monitor and document the extent to which the patient is using the medication as prescribed and assess for aberrant medication behaviours.