Legal Access to Cannabis Based Medicines

Q. What are the legal access pathways for doctors wishing to prescribe a cannabis medicine?

Generally, medicines supplied in Australia must be assessed by the Australian Government's Therapeutic Goods Administration (TGA) for quality, safety and efficacy, and registered on the Australian Register of Therapeutic Goods (ARTG).

The TGA may approve the supply of unregistered cannabis medicines under the following pathways:

- a Clinical Trial
- the Authorised Prescriber Scheme
- the Special Access Scheme.

Q. Who can prescribe a cannabis medicine?

NSW medical practitioners can legally prescribe a cannabis medicine for a patient if they believe it is an appropriate treatment option for their patient's health condition and they have obtained the relevant authorities.

The patient's current treating medical practitioner, with whom there is an established therapeutic relationship, is the most appropriate person to prescribe, and subsequently monitor outcomes of, a cannabis medicine. If applicable, this should follow consultation and consensus with other treating medical practitioners in the patient's care team. Patients do not need to be referred to a 'cannabis clinic'.

There is no charge from the TGA or NSW Health to apply for an authority to prescribe.

Q. What approvals are required before a cannabis medicine can be lawfully prescribed?

Doctors require an approval from the TGA before they can prescribe an unregistered Schedule 8 (S8) cannabis medicine. In assessing an application for a prescriber to import or supply an unregistered cannabis medicine, the TGA considers the prescriber's expertise, the suitability of the medicine to treat the patient's condition and the quality of the medicine.

An application to NSW Health must also be made where it is for:

- prescribing or supply to a drug dependent person, including a person treated under the Opioid Treatment Program, or
- prescribing or supply of an unregistered medicine for a clinical trial.

A NSW Health authority is not needed to prescribe a Schedule 4 cannabis medicine.

Given the risks associated with unregistered medicines, it is expected that medical practitioners are confident in prescribing a cannabis medicine for the condition it is being requested for, and that the patient is fully informed of what is known of potential benefits and harms. The TGA may request confirmation of the therapeutic relationship with a patient and information regarding the involvement of other members of the patient's treating team.

Q. Why is a NSW Health authority required for these patient groups?

NSW Health will maintain control over the prescribing and supply of S8 cannabis medicines to vulnerable patient groups i.e. those with substance use problems or children where the long-term benefits and harms are uncertain.

Medical practitioners will not need a NSW authority to prescribe or supply S8 cannabis medicines in most circumstances as the Australian Government requirements to access unregistered medicines offer a sufficient level of protection to these patients.

Q. What conditions can cannabis medicines be prescribed for?

Applications to prescribe unregistered medicines are assessed by the TGA on a case-by-case basis. There is no pre- determined list of conditions for which a cannabis medicine can be prescribed. Each application from a prescribing doctor will be considered on its merits.

An application to the TGA from a doctor to prescribe must be accompanied by clinical evidence about use of the product to allow for an assessment of potential benefits and harms. It is expected that all registered medicines or non-drug treatments will have already been explored.

Q. Which cannabis medicines can be prescribed?

Four cannabis medicines have already been formally assessed for quality, safety and efficacy, either in Australia or by an overseas medicines regulator:

- Sativex® (nabiximols) is registered in Australia by the TGA on the ARTG for the treatment of moderate to severe spasticity associated with multiple sclerosis.
- Marinol® (dronabinol) is synthetically manufactured and registered in the US by the Food and Drug Administration (FDA) for the treatment of anorexia in patients with AIDS, and for the management of chemotherapy-induced nausea and vomiting where standard anti-nausea treatments have failed.
- Cesamet® (nabilone) is synthetically manufactured and registered in the US by the FDA for the management of chemotherapy-induced nausea and vomiting.
- Epidyolex® (cannabidiol) is plant-derived, and registered in Australia by the TGA on the ARTG for the management of Dravet and Lennox-Gastaut syndromes for patients 2 years of age and older.

Applications to prescribe are not limited to the small number of products that have been formally registered here or overseas. However, to be prescribed in Australia, a cannabis medicine must be legally produced and manufactured to appropriate quality standards with evidence supporting the use of the type of product for the patient's indication.

Products that might be accessed from unregulated sources, including oils, tinctures and plant material, can contain harmful substances and will not be authorised.

Q. Who can medical practitioners contact for clinical advice?

General practitioners, community pharmacists and rural health practitioners considering the use of a cannabis medicine as a treatment for their patient may contact the John Hunter Hospital Pharmacy Department for guidance, via HNELHD-JHHPharmacy@health.nsw.gov.au

Further information

For general practitioners, community pharmacists and rural health practitioners:

email: HNELHD-JHHPharmacy@health.nsw.gov.au

Visit the NSW Health website

- www.health.nsw.gov.au/pharmaceuticalcannabismedicines