CANNABIS MEDICINES use in Hospitals

Access

To be prescribed in Australia, cannabis medicines must be legally produced or imported. Access can occur via the following pathways:

1. **A registered** product on the Australian Register of Therapeutic Goods (ARTG) such as Sativex® (nabiximols) OR
2. **An unregistered** therapeutic good, accessed via:

   a. Special Access Scheme (SAS); b. Authorised Prescriber scheme or c. Clinical Trial scheme

Possession of illegal or 'black market' cannabis (i.e. cannabis not accessed via pathways above) is prohibited even when patients are registered with the Medicinal Cannabis Compassionate Use Scheme. As such, NSW Health staff cannot store or administer these preparations in the hospital, nor administer them when providing care in the home setting. For advice regarding processes where an illegal cannabis preparation is brought onto hospital premises, refer to IB2019_041 *Schedule 8 Cannabis Medicines and Unregistered Schedule 8 Medicines Information Bulletin*.

General principles for use

- Cannabis medicines are **never** first line therapy.
- There is only limited evidence for the effectiveness of various cannabinoids in some conditions. Each prescriber must weigh up potential benefits and harms and determine whether a specific product may be clinically justifiable for the condition being treated based on the evidence and circumstances.
- Clinicians must obtain informed consent from the patient when prescribing unregistered cannabis medicines.
- Therapeutic Goods Administration (TGA) approval for unregistered products is considered on a case-by-case basis, except via the authorised prescriber scheme.
- The TGA has approved SAS applications including, but not limited to, the following indications: chemotherapy-induced nausea and vomiting, refractory paediatric epilepsy, palliative care indications, cancer pain, neuropathic pain, spasticity from neurological conditions, anorexia and wasting associated with chronic illness (such as cancer).
- Refer to the TGA and NSW Cannabis Medicines Prescribing Guidance for information relating to various conditions. The NSW Cannabis Medicines Advisory Service (NSW CMAS) can provide literature reviews, taking into account an individual patient's circumstances.

Hospital approval process

TGA approval is required **for all unregistered cannabis medicines** (S4 & S8)

NSW Authority **IS REQUIRED** to prescribe & supply S8 cannabis medicine*:

- To a drug dependent person (whether for a registered or unregistered product) including a person treated under the Opioid Treatment Program.
- To a participant in a clinical trial of an unregistered product.

  NB: Requirements and/or conditions of Commonwealth Approval (CTN/CTX), Human Research Ethics Approval, or of the National Health and Medical Research Council (NHMRC) must also be satisfied.

NSW Authority **IS NOT REQUIRED** to prescribe & supply S8 cannabis medicine:

- When continuing treatment during hospitalisation (including in the Emergency Department) and on discharge, when the treatment was initiated outside hospital, even if the patient had required a NSW Authority when not hospitalised¥.

*NSW Authority is also required to prescribe & supply compounded cannabis medicines. Prescribers should contact the NSW Ministry of Health for advice.
¥A doctor can initiate treatment of a hospital inpatient with a registered S8 which would otherwise require a NSW Authority, for up to 14 days following admission (regardless of whether the patient is still an inpatient); Authority is required after that.

For administration to a **child (<16 years)**, an exemption under the *Children and Young Persons Act 1998* must have been issued to commence 'special medical' treatment by the medical practitioner. When an exemption has been issued by the Secretary Communities and Justice, treatment may be continued in hospital. The medical practitioner may contact the NSW Ministry of Health to seek clarification. NB: only one NSW government-issued document is required.

- **Applications for hospital inpatient prescribing & supply** of cannabis medicines **must adhere to** the relevant **Drug and Therapeutics Committee (DTC) requirements**. The DTC is responsible for overseeing all formulary and individual patient usage (IPU) approvals, in accordance with PD2016_033 *Approval process of medicines for use in NSW public hospitals.*
- The NSW Authority document outlines conditions of supply (e.g. expiry date). If another doctor wishes to prescribe (for example after a patient is discharged), that doctor will need to obtain an Authority (and the first doctor's Authority will be revoked).
- Refer to the Information Bulletin IB2019_041 for further information regarding NSW Authority requirements.
- The Commonwealth Standard for Medicinal Cannabis (TGO 93) specifies minimum quality requirements for medicinal cannabis products in Australia. However, unregistered medicines are not assessed for quality, safety or efficacy by the TGA.

Active ingredients and Scheduling

- Products may contain varying amounts of cannabinoids. The two main cannabinoids are tetrahydrocannabinol (THC), which has psychoactive properties and cannabidiol.
- Nabiximols is a complex of cannabinoids in a standard formulation registered for use in Australia. Some synthetically manufactured cannabinoids, oral dronabinol and nabilone, are approved medicines in the USA but are not registered medicines in Australia.
- Products are **Schedule 4** when containing CANNABIDIOL for therapeutic use where the **cannabinoids** component in the preparation contains at least 98% cannabidiol and 2% or less of other cannabinoids found in cannabis.
- All other cannabis products are **Schedule 8** and may include the following active ingredients alone or in combination:
  - DRONABINOL (synthetic delta-9-THC) when prepared and packed for therapeutic use
  - NABILONE
  - NABIXIMOLS: Each mL of Sativex® oromucosal spray contains 80 mg of extracts corresponding to 27 mg delta-9-THC and 25 mg cannabidiol and lesser amounts of other cannabinoids (56 mg total cannabinoids)
  - TETRAHYDROCANNABINOLS

  (refer to the latest Poisons Standard for exceptions)

Dispensing requirements

Receipt of a prescription or medication chart. NB: emergency telephone/ email/ fax orders are **not** permitted for unregistered S8 medicines.

Usual requirements for an S8 medicine apply. e.g. adequate directions for use, handwritten quantity in words & figures on prescriptions.

Prescriptions for Schedule 8 cannabis medicines issued **after 30 September 2019** do NOT need to include a **NSW Authority number** on the prescription.

All supplies & receipts for S8 medicines must be **recorded in a drug register**. If used in a clinical trial, a record of the NSW authority number must also be made in the clinical trial records.

Use of patient's own stock: Ensure product is identifiable with appropriate authorisation & labelling. Confirm with regular pharmacy and/or prescriber. Inpatient treatment may then be continued without a NSW Authority.

Formulations, dosing and storage considerations

- Use of cannabinoid-containing medicines is a rapidly evolving area of medicine and the majority of products remain unregistered in Australia.
- Clinicians are advised to contact NSW CMAS for information about formulations, dosing, potential drug/disease interactions & monitoring guidance for individual patient care.
- Product dosage regimens (written by sponsors) have not been evaluated by the TGA and should be verified by an expert drug information pharmacist/service (e.g. NSW CMAS). Doses vary widely and often incorporate commencement at low doses and slow up-titration to reduce the risk of experiencing adverse effects. Potential for drug interactions may not be well documented in the literature and requires checking.
- There are a variety of formulations and strengths€ including:
  - Products containing similar amounts of cannabidiol & THC
  - THC-predominant products.
  - Cannabidiol-predominant products.
  - Oral oils, oromucosal/oral-buccal sprays, oral capsules, lozenges, flos/granulate for inhalation, crystals, tinctures, topical balm and transdermal patches.
  - Products administrated via inhalation (e.g. flos/granulate) requiring a vaporising device.

  € Availability of unregistered cannabis medicines is subject to change
- S8 cannabis medicines must be stored separately & securely, as per requirements for all S8 medicines. Some products require refrigeration – refer to storage requirements.

Policy information

- IB2019_041 *Schedule 8 Cannabis Medicines and Unregistered Schedule 8 Medicines Information Bulletin*. NSW Health. 16 October 2019.
- NSW-based clinicians should obtain information tailored to the patient-specific clinical context from the NSW CMAS including, but not limited to, clinical & scientific evidence & clinical trials.
- Information on NSW-based regulatory requirements for prescription and supply of S8 Cannabis Medicines, including prescriber, dispensing and storage requirements is available from NSW Ministry of Health Pharmaceutical Services.

Other online resources

- Information on research, publications and resources including prescribing guidance documents is available from Australian Centre for Cannabinoid Clinical and Research Excellence
- Information on clinical trials, the medicinal cannabis compassionate use scheme and other resources are available from Centre for Medicinal Cannabis Research and Innovation
- Online learning resources for prescribers are available from Royal Australian College of General Practitioners (RACGP)
- Information on cannabis products licence requirements and travelling is available from The Office of Drug Control.

NSW TAG collaborated with NSW Cannabis Medicines Advisory Service in the development of this document.