NSW Medicinal Cannabis Guidance

This is a summary of the requirements for the supply of medicinal cannabis and should not be considered exhaustive. Pharmacists should always refer to the NSW Poisons and Therapeutic Goods Regulation 2008, Poisons and Therapeutic Goods Act 1966 and AHPRA Codes, Guidelines and Policies.

Pharmacist Requirements

- Pharmacists must comply with the NSW Poisons and Therapeutic Goods Act 1966 and with the Poisons and Therapeutic Goods Regulation 2008, including the supply, storage and record keeping requirements.
- Pharmacists must practice in accordance to the AHPRA Shared Code of Conduct and should not enter into any arrangement for exclusive supply of medicinal cannabis with a prescriber or third party provider.
- Pharmacists should be aware of the AHPRA raised concerns over emerging models of care and the AHPRA joint statement on professional responsibilities for prescribing and dispensing medicines.

Patient Information

Medicinal cannabis should be prescribed and supplied for a purpose and dosage that is in accordance with therapeutic standards.

Pharmacists should:

- review the use of medicinal cannabis with the patient as with any other medicine, and counsel on safe and appropriate use as prescribed.
- utilise SafeScript NSW to establish if any S8 or other monitored medicine has been supplied and assess safety.
- ensure patient is aware of the cost of medicinal cannabis products prior to dispensing and ordering.

Clinical Information

- The TGA has published Medicinal cannabis guidance
- Expert clinical guidance is available via the John Hunter Hospital Pharmacy Department, and they can be contacted via email at: HNELHD-JHHPharmacy@health.nsw.gov.au
- The RACGP A primer on medicinal cannabis safety and potential adverse effects article provide guidance on appropriate dosing and potential adverse effects.
- Pharmacists should ensure patients understand the impact of medicinal cannabis on driving, operating machinery and other interactions that may impair function.
- In NSW, it is illegal for patients taking medicinal cannabis products containing THC to drive. This should be discussed with all patients prescribed THC, to ensure that they are aware they cannot drive. Further information is available here.

Prescriptions

All medicinal cannabis scripts legally require:

- Date of issue, name, date of birth and address of the patient.
- Name, designation, address and contact details of the prescriber.
- The name, strength (NOT a range of strengths), dosage and quantity
 of each active cannabis medicine ingredient. In some instances, the
 use of a brand name may adequately identify the active ingredient
 and strength.
- For S8 medicines, the quantity written in words and figures. Noting, the quantity supplied must conform with the dose and directions prescribed.
- If the Schedule 8 prescription has repeats, a repeat interval written on the prescription.
- Adequate directions for use.
- Signed by the prescriber, unless a conformant electronic prescription.
- Labelled with a dispensing label, with the same details required for any dispensed medicine.

Emergency supply provisions do not apply for unregistered Schedule 8 medicines. To dispense an unregistered Schedule 8 medicine a valid prescription is required.

TGA approvals for unapproved therapeutic goods either via the Special Access Scheme (SAS) or the Authorised Prescriber (AP) pathway are obtained and current at the time of dispensing.

Vaping Devices

Devices used to vape medicinal cannabis must either be listed in the Australian Register of Therapeutic Goods or otherwise be approved or authorised via the special access scheme (SAS) or the authorised prescriber (AP) pathway.

Substitution: The prescription is valid for dispensing only as prescribed, including the exact strength/s of active ingredient/s prescribed, and the brand-named product if specified by the prescriber. Substitution of products is not allowed, even if products are within the same TGA category.

Advertising

 Schedule 4 medicines, Schedule 8 medicines, and products that are not ARTG registered or listed cannot be advertised in Australia, to either consumers or healthcare professionals.

Storage

- S8 medicines must be kept in a locked safe at all times.
- S8 medicines requiring refrigeration must be kept in a locked refrigerator that is not accessible to the public, secured to the premises, and only able to be accessed by a pharmacist.
- Stock checks for S8 medicines must be conducted every March and September. To meet professional practice requirements, pharmacists should undertake a stock check as frequently as needed to detect any discrepancies.
- A pharmacist cannot order or hold stock of any unregistered medicine unless they have received a prescription from an AP prescriber, or a prescription plus an SAS form for the medicine. Ordering and storing stock in anticipation of a prescription is not a valid reason to hold stock, except if stock is for repeats authorised on the original prescription, for a particular patient.
- Pharmacists should have a process for storage and handling of medicinal cannabis products that are ordered in response to a prescription presented to the pharmacy, and not collected by the patient.

Records

- All supplies and receipts of S8 medicinal cannabis medicines must be recorded in a drug register on the day of the transaction. A separate page of the register must be used for each brand name and each strength of the Schedule 8 medicine.
- Unwanted Schedule 8 cannabis medicines can only be destroyed by a person authorised to destroy Schedule 8 drugs. Information for community pharmacies can be found at Destruction of Schedule 8 medicines at community pharmacies.

Compounding

- The compounding of cannabis medicines is not allowed unless the SAS or AP specifically approves the supply of a compounded cannabis medicine.
- The compounding of medicines that are of a close formulation to an available and suitable commercial product and would not be likely to produce a different therapeutic outcome should not occur.
- A separate NSW Ministry of Health approval number is required for S8 cannabis medicines extemporaneously compounded. A pharmacist can only dispense such a prescription if the NSW Health approval number is on the prescription.



