# Cannabis medicines in residential aged care facilities



Sativex<sup>®</sup> and Epidyolex<sup>®</sup> have been approved for use by the Therapeutic Goods Administration (TGA). All other cannabis medicines are unregistered.

## Legal pathways for prescribing an unregistered cannabis medicine

In NSW, any medical practitioner can prescribe a cannabis medicine if they believe it is an appropriate treatment option for their patient and have obtained the necessary authority, having evidence that it may effectively treat the patient's condition. There is no need for patients to attend a special clinic.

Doctors require authorisation from the TGA to prescribe an unregistered cannabis medicine. There are three possible pathways for TGA authorisation:

- The Special Access Scheme medical practitioners may seek approval to prescribe an unapproved therapeutic good for a specific patient.
  See: www.tga.gov.au/form/special-access-scheme
- The Authorised Prescriber Scheme medical practitioners may seek authority to become an 'Authorised Prescriber' of a specified unapproved therapeutic good or class of unapproved therapeutic goods to specific patients or classes of patients with a particular medical condition. See: <u>www.tga.gov.au/</u> <u>form/authorised-prescribers</u>
- Clinical Trial schemes more information for medical practitioners is available at: <u>Prescribing pathways</u> <u>– Cannabis medicines (nsw.gov.au)</u>.

In addition to TGA approval, a doctor must also obtain authority from NSW Health to prescribe a Schedule 8 cannabis medicine for a patient who is drug dependent, under 16 years of age or for a clinical trial of an unregistered medicine. For further information, visit: <u>www.health.nsw.gov.au/pharmaceutical/</u> <u>cannabismedicines/Pages/default.aspx</u>.

Any cannabis product not imported or manufactured and prescribed under Australian Government authority is a Prohibited Drug under the <u>Drug Misuse and Trafficking Act</u> <u>1985 (NSW)</u>. Possession, prescribing and supply of Prohibited Drugs carry penalties including heavy fines and imprisonment.

#### Importation

Importation of cannabis medicines is controlled by the Office of Drug Control. There are two pathways for importation of cannabis medicines:

- Per patient importation by a medical practitioner if they believe a cannabis medicine is suitable for a particular patient; or
- Importation by an importer licensed by the Office of Drug Control.

Further information about importation of cannabis medicines can be found here: <u>www.odc.gov.au/import-and-export</u>.

## Storage conditions for cannabis medicines in residential aged care facilities

Residential aged care facilities (RACFs) must ensure all medicines, including self-administered medicines, are stored safely and securely to protect residents, staff and visitors. RACF storage practices should maintain the quality of medicines and follow recommended storage conditions as outlined on the Product Information for registered medicines. Medicine storage policy and procedures must be consistent with the requirements of the NSW Poisons and Therapeutic Goods legislation and any relevant Commonwealth legislation and policy including the Commonwealth <u>Guiding Principles for</u> <u>Medication Management in Residential Aged Care Facilities</u>.

RACFs should also consider storage issues such as refrigeration and stock control and rotation. Whether a cannabis medicine will require refrigeration will depend on the specific product and will be stated on the product label and/or advised by the dispensing pharmacist. RACF staff should also check product expiry dates when arranging storage.

The NSW Poisons and Therapeutic Goods Regulation 2008 (Regulation) sets out storage requirements applicable to 'nursing home' RACFs! which are explained in the IB2003/10 Guide to the handling of medication in nursing homes in NSW. Appropriate storage arrangements for a cannabis medicine will depend on whether the product is a Schedule 4 (Prescription Only) or Schedule 8 (Drugs of Addiction) medicine. Most cannabis medicines are Schedule 8 (S8) medicines, and must be stored the same as all other S8 medicines, recorded in a drug register and any loss reported to the Ministry of Health. For further information, visit: <u>www.health.nsw.gov.au/</u> <u>pharmaceutical/Pages/lost-stolen-drugs.aspx</u>.

S8 medicines must be stored in a separate cupboard to other medication, preferably a metal safe, attached to part of the ward and locked when not in immediate use. The access key should be kept separately from other keys and must be on the person of the registered nurse in charge of the ward or their delegate, who must be a registered nurse.

Schedule 4 (S4) medicines must be stored out of resident and visitor access in a locked cupboard, which is securely attached to part of the premises, on a shelf in a locked room, in a locked medication trolley, or locked drawer. These storage facilities must be locked when not in immediate use and access keys must be held separately from other nursing home keys, so medication can only be accessed by authorised persons.

RACFs not licensed as "nursing homes" are not under the Regulation for resident medicines storage, administration and recording but can use <u>IB2003/10</u> to inform best practice and as a useful guide for such facilities.

#### Administration

Nurses/carers at RACFs must administer cannabis medicines according to general practitioner (GP) instruction, as shown on the pharmacy dispensing label and the patient medication chart (if any).

#### Disposal

RACFs should ensure unwanted, ceased or expired medicines are disposed of safely to avoid accidental poisoning, misuse and environmental contamination.

Expired or redundant S8 cannabis medicines must not be returned to the dispensing pharmacy and should be destroyed on the premises of the RACF under the supervision of an authorised person? A retail pharmacist who supplies S4 or S8 medication to a nursing home or to a resident of a nursing home is authorised to destroy unwanted S8 drugs on the nursing home's premises in the presence of the Director of Nursing. The drugs must be destroyed in a way that does not cause environmental or public harm and so that the drugs cannot be recovered. The pharmacist must record the destruction by signing an entry on the nursing home's drug register and the Director of Nursing must countersign.

S4 medicines no longer being used for the resident they were dispensed for cannot be kept for administration to another resident. Arrangements should be made with the supplying pharmacist for the return of S4 medication to the pharmacy for disposal via a pharmaceutical waste system. The *Return of Unwanted Medicines* program provides appropriate disposal of unwanted medicines via community pharmacies. RACFs can also have an onsite pharmaceutical waste container for secure medication disposal.

### **Further information**

#### For health professionals:

For information about using a cannabis medicine to treat a patient, general practitioners, community pharmacists and rural health practitioners may contact the John Hunter Hospital Pharmacy Department for guidance, via <u>HNELHD-JHHPharmacy@health.nsw.gov.au</u>.

For information about authorisations to prescribe, contact the Pharmaceutical Regulatory Unit, NSW Ministry of Health on (02) 9391 9944 or <u>MOH-CannabisMedicinesApplicationsNSW@health.nsw.gov.au</u>.

#### For patients:

Email the Centre for Medicinal Cannabis Research and Innovation via MOH-CannabisTrial@health.nsw.gov.au

<sup>1</sup> 'Nursing home' in this context refers to RACFs which on 30 June 2014 held one or more high level of residential care allocated places approved under the *Aged Care Act* 1997 (Cth). For further information, see: <a href="https://www.health.nsw.gov.au/pharmaceutical/Pages/residential-care-facilities.aspx">www.health.nsw.gov.au/pharmaceutical/Pages/residential-care-facilities.aspx</a>.

<sup>2</sup> As per the Regulation.