Schedule 8 Cannabis Medicines and Unregistered Schedule 8 Medicines

Summary This Information Bulletin is to provide guidance on prescribing and dispensing Schedule 8 cannabis medicines and unregistered Schedule 8 medicines

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INFORMATION BULLETIN

SCHEDULE 8 CANNABIS MEDICINES AND UNREGISTERED SCHEDULE 8 MEDICINES

PURPOSE

This Information Bulletin provides guidance on:

1. prescribing and dispensing registered and unregistered Schedule 8 cannabis medicines, and
2. prescribing and dispensing unregistered Schedule 8 medicines including compounded medicines, and
3. storage of refrigerated Schedule 8 and Schedule 4 Appendix D medicines in NSW public health facilities.

BACKGROUND INFORMATION

Regulation Amendment

As at 30 September 2019, to prescribe and supply a Schedule 8 cannabis medicine, an authority under the NSW *Poisons and Therapeutic Goods Act 1966* (NSW Authority) is required only in specific circumstances. See section Prescribing and Dispensing Schedule 8 Cannabis Medicines. This Bulletin has been updated to reflect these amendments.

Definitions

For the purpose of this Information Bulletin:

Schedule 8 cannabis medicine means a therapeutic good containing cannabinoids derived from the cannabis plant, prepared or packed for human therapeutic use, and included in Schedule 8 of the NSW Poisons List or Poisons Standard, or synthetically made cannabinoids such as dronabinol and nabilone.

Cannabis medicines containing cannabidiol as at least 98% of the total cannabinoid content are Schedule 4 medicines, and are out of scope of this document.

Compounded Schedule 8 medicine means any therapeutic good prepared in or for a hospital pharmacy that consists of a Schedule 8 substance, except:

a) a registered medicine reconstituted prior to dispensing;

b) a registered medicine prepared for administration in accordance with the approved Product Information; or

c) a registered medicine repacked without a change to the formulation (such as transferring the contents of an ampoule into a syringe).

Commonwealth approval to access unregistered medicines

Generally, medicines used in Australia must be registered on the Australian Register of Therapeutic Goods (ARTG), unless exempted from registration, or approved for supply as an unregistered good, by the Therapeutic Goods Administration (TGA).

Unregistered medicines are not assessed for quality, safety or efficacy by the TGA.

To prescribe an unregistered medicine in Australia, the prescriber must obtain an approval to supply an unregistered good issued under the Commonwealth's *Therapeutic Goods Act 1989* by the TGA (Commonwealth Approval), under one of:

- Special Access Scheme, or
- Authorised Prescriber scheme, or
- Clinical Trial schemes.

Additionally, the use of **any** unregistered medicine (Schedule 8 or not) in a NSW public health facility must be approved by the Drug and Therapeutics Committee (DTC) of the hospital or Local Health District, whether the product is to be supplied by the hospital for individual patient use or as patient's own stock, in accordance with PD2016_033 *Approval Process of Medicines for Use in NSW Public Hospitals*. A NSW Authority, if required, must be in place before the DTC can consider approval for the use of an unregistered Schedule 8 medicine in hospital.

Cannabis Medicines

Most cannabis medicines are unregistered. The only cannabis medicine registered on the ARTG at the time of publication is *Sativex*® (nabiximols oromucosal spray).

Unregistered Schedule 8 cannabis medicines may be prescribed for human therapeutic use if the prescriber and product meet certain criteria. The cannabis must have been lawfully grown and manufactured in Australia or permitted to be imported by the Commonwealth, and must conform with the Commonwealth standard that specifies minimum quality requirements for medicinal cannabis products TGO 93 *Standard for Medicinal Cannabis*.

Administration, possession, supply and manufacture of a cannabis preparation which has not been lawfully prescribed or supplied remains an offence under the *Drug Misuse and Trafficking Act 1985* (NSW).

Unlike registered medicines which typically have one or two active ingredients, the cannabis plant contains a complex of more than 400 compounds including flavonoids and terpenoids and approximately 100 cannabinoids other than tetrahydrocannabinol or cannabidiol. These cannabinoids have individual, interactive, and even entourage effects (effects of a compound that are only appreciable in the presence of other compounds) that are not fully understood and that contribute to the pharmacological effect of cannabis.

Although clinical trials and studies in animal models of some conditions have been conducted with individual cannabinoids (e.g. tetrahydrocannabinol or cannabidiol), as cannabis has so many constituents, the results of studies with individual cannabinoids cannot be extrapolated to cannabis plant material and plant extracts, and vice versa.[1]

Unlike registered medicines, the composition of unregistered cannabis preparations could vary substantially in content of tetrahydrocannabinol, cannabidiol or other cannabinoids.

Individual synthetically manufactured natural cannabinoids are approved medicines in the USA in the form of oral dronabinol and nabilone, but these are not registered medicines in Australia. Nabiximols is a complex of cannabinoids in a standard formulation approved in the UK and in Australia.

[1.] D'Souza DC, Ranganathan M. Medical marijuana, is the cart before the horse? JAMA 2015; Volume 313 (24); 2431-2

PRESCRIBING AND DISPENSING SCHEDULE 8 CANNABIS MEDICINES

A NSW Authority is now only required to prescribe and supply a Schedule 8 cannabis medicine:

- to a drug-dependent person* (registered or unregistered) including a person treated under the Opioid Treatment Program, or
- that is a compounded medicine, or
- for a clinical trial (if unregistered).

* *A drug-dependent person means a person who has acquired, as a result of repeated administration of any of the following drugs, an overpowering desire for the continued administration of a drug of addiction (Schedule 8), or a prohibited drug within the meaning of the Drug Misuse and Trafficking Act 1985 (including but not limited to heroin, methylamphetamine or cocaine).*

Additionally, when a medical practitioner is to carry out special medical treatment involving the administration of a Schedule 8 cannabis medicine to a child (aged under 16 years), an exemption under the *Children and Young Persons (Care and Protection) Act 1998* must be sought, by making an application to the Ministry. If the child has been undergoing treatment with the Schedule 8 cannabis medicine prior to admission, an exemption may already be in place. The medical practitioner may contact the Ministry to seek clarification.

A medical practitioner does not need a NSW Authority in the following circumstances:

- to continue treatment with a Schedule 8 cannabis medicine for a patient in hospital, if the patient was subject of an authority immediately prior to hospital admission
- to continue treatment with a Schedule 8 cannabis medicine for a patient in community, if the patient is subject of an authority, and the medical practitioner is practising at the same premises that the holder of the authority was practising at when the authority was issued.

In an emergency, a medical practitioner may direct the administration of any Schedule 8 cannabis medicine to a hospital patient orally, by telephone, by e-mail or by facsimile. However, a medical practitioner may NOT direct the dispensing of an **unregistered** Schedule 8 cannabis medicine orally, by telephone, by e-mail or by facsimile.

All requirements for writing Schedule 8 prescriptions apply – see in NSW Health PD2013_043 *Medication Handling in NSW Public Health Facilities*.

Cannabis medicines in clinical trials

NSW Authority and Commonwealth Approval to prescribe and supply an unregistered Schedule 8 cannabis medicine for a clinical trial are required. Only a medical practitioner can prescribe an unregistered cannabis medicine for a clinical trial. Any requirements or conditions of the Commonwealth Approval (CTN/CTX), Human Research Ethics Approval, or of the National Health and Medical Research Council (NHMRC) must be complied with.

Prescribing unregistered Schedule 8 cannabis medicines for children

When a medical practitioner is to carry out special medical treatment involving the administration of a Schedule 8 cannabis medicine to a child (under 16 years), an exemption under the *Children and Young Persons (Care and Protection) Act 1998* must be sought, by making an application to the Ministry. If the child has been undergoing treatment with the Schedule 8 cannabis medicine prior to admission, an exemption may already be in place. The medical practitioner may contact the Ministry to seek clarification.

Hospital pharmacy dispensing of Schedule 8 cannabis medicines

A pharmacist may only dispense an unregistered Schedule 8 cannabis medicine on receipt of a prescription or a medication chart. Dispensing on an emergency telephone/email/fax order is not permitted.

All the usual requirements for a Schedule 8 medicine, such as adequate directions for use, handwritten quantity in words and figures and repeat intervals apply.

The supply of Schedule 8 medicines on discharge must accord with PD2011_015 *Care Coordination: Planning from Admission to Transfer of Care in NSW Public Hospitals*.

Schedule 8 cannabis medicines administration within a patient care area

In an emergency, a medical practitioner may direct the administration of any Schedule 8 cannabis medicine to a patient in the hospital, orally, by telephone, by electronic mail or by facsimile on a medication chart.

Where a pharmacist dispensed and labelled unregistered Schedule 8 cannabis medicine is brought into the hospital as patient's own stock, having been commenced prior to hospital admission, hospitals must check that use of the product is appropriately authorised. Contact should be made with the pharmacy or prescriber named on the dispensing label in the first instance. A medical practitioner may direct an order for administration of the patient's own stock of the Schedule 8 cannabis medicine to continue treatment on a medication chart (or electronic medication management system) without a NSW Authority.

Illegal cannabis plants and cannabis preparations

Some patients may be using illegal 'black market' cannabis preparations in expectation of symptom relief or hoping to modify the course of a disease. Possession of these prohibited drugs/plants is illegal under the *Drug Misuse and Trafficking Act 1985* (NSW), even where patients are registered with the NSW Government Medical Cannabis Compassionate Use Scheme. See https://www.medicinalcannabis.nsw.gov.au/patient- access/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. These preparations cannot be legally prescribed.

A history of use of cannabis preparations must be taken, and disclosure of use encouraged. The risks of using these preparations of unknown composition and concentration of cannabinoids and other potentially dangerous substances, and the risk of drug interactions (some unpredictable or undocumented), must be discussed with the patient/carers.

It is recommended and good practice to document substance use in the patient's clinical record. This should include information about advice given, any changes to therapy, and the decision of the patient. Ongoing open communication remains essential.

Notwithstanding the above, patients should be made aware that continued use of any illegal cannabis preparation remains unlawful.

If a patient brings an illegal cannabis preparation onto hospital premises, the patient should be requested to have a carer remove the preparation from the hospital premises, or it should be dealt with as otherwise provided under a local protocol.

If harm has resulted from use of an illegal cannabis preparation, and the supplier can be identified, the hospital should consider bringing the matter to the attention of NSW Police.

PRESCRIBING AN UNREGISTERED SCHEDULE 8 MEDICINE

Normally, a NSW Authority is required to prescribe and supply any compounded Schedule 8 medicine, including cannabis medicines. However, an exemption is in place to exclude Schedule 8 medicines compounded by a pharmacist in a public hospital pharmacy for the treatment of a patient of a public hospital, or manufactured under a contract for the public hospital, from requiring a NSW Authority.

REFRIGERATED STORAGE OF SCHEDULE 8 AND SCHEDULE 4 APPENDIX D MEDICINES

Storage in hospital pharmacy

Schedule 8 medicines stored in a hospital pharmacy must be kept in a safe (or vault) securely attached to the premises, and locked when not in immediate use - see section 5.3.4 of NSW Health Policy Directive PD2013_043 *Medication Handling in NSW Public Health Facilities*, unless the medicine requires refrigeration.

If a Schedule 8 medicine requires refrigeration, it may be kept in a refrigerator, rather than a safe, that is in a room to which the public does not have access.

The refrigerator must be securely attached to the premises and locked when not in immediate use. Hospital engineering may be able to assist with fixing and fitting the refrigerator.

The usual requirements apply to access to a Schedule 8 medicine stored in a pharmacy, including:

- keeping the device (including a key) on the person of a pharmacist who is at the premises, or a separate safe that can be unlocked only by a pharmacist

- disclosing a code or combination that is used to securely lock the refrigerator only to a pharmacist.

Unscheduled, Schedule 2, 3 or 4 therapeutic goods requiring refrigeration may be stored with Schedule 8 medicines, provided only a pharmacist has access to the refrigerator. If other goods are required to be kept in the refrigerator, an exemption must be sought from the Ministry.

Storage in a patient care area

A **Schedule 8** medicine in a patient care area must be stored:

a) in a cabinet, safe or room; apart from all other medicines except other Schedule 8 and Schedule 4 Appendix D medicines; kept securely locked when not in immediate use; and to which the public does not have access, **or**

b) if requiring refrigeration, in a locked refrigerator securely attached to the ward, **or** in a refrigerator that is in a locked room; apart from all other medicines except other Schedule 8 and Schedule 4 Appendix D medicines; kept securely locked when not in immediate use; and to which the public does not have access.

If goods other than Schedule 4 Appendix D medicines are to be kept in the refrigerator, the Schedule 8 medicines must be kept separated from them, such as in a locked box attached to the refrigerator. Hospital engineering may be able to assist with fixing and fitting the refrigerator to the premises, or the locked box to the refrigerator.

The usual requirements apply to access to a Schedule 8 medicine stored in a patient care area, including:

- keeping the device (including a key) on the person of a nurse or midwife whenever it is in the ward, and is removed from the ward whenever there is no nurse or midwife in the ward, or in a separately locked safe to which only a nurse or midwife has access, and
- any code or combination that is required to unlock the locked cabinet, safe or room or refrigerator is not divulged to any unauthorised person.

An alternative to the usual *Poisons and Therapeutic Goods Regulation 2008* requirements for **Schedule 4 Appendix D** medication storage in patient care areas (ward/clinic / unit) applies to the following medications:

- darbepoetin
- epoetins
- erythropoietins
- lorazepam injections.

The refrigerator containing these Schedule 4 Appendix D medications may be kept in a locked room containing any other medications. Access to this room must be

restricted to staff authorised by the registered nurse / midwife in charge of the patient care area.

The medications must be accounted for under a local protocol approved by the Hospital / LHD Drug and Therapeutics Committee that ensures the detection and reporting of any loss or misappropriation.

Methods to mitigate and detect loss or misappropriation described in the protocol could include:

- Maintenance of register to document the receipt, use and balance on hand of medication.
- Limit of supply to patient labelled medications (that is, no ward stock / imprest supply).
- Regular audit of iPharmacy dispensing reports of patients labelled supplies to the patient care area.
- Regular audit and reconciliation of pharmacy inventory reports of imprest supplies to the patient care area against medication administration records.

The requirement to report any loss or theft of an accountable medication (Schedule 4 Appendix D and Schedule 8 medications) remains (see section 6.16 of NSW Health Policy Directive PD2013_043 '*Medication Handling in NSW Public Health Facilities*').

Alternatives to storage requirements under the Poisons and Therapeutic Goods Regulation 2008 may be granted for storage of other refrigerated accountable medications in hospital pharmacy or patient care areas on application to the NSW Ministry of Health.

Contact details for further information

Chief Pharmacist Unit, NSW Ministry of Health:

For enquiries on NSW Authority, or on prescribing, dispensing or storage of medicines
Website: https://www.health.nsw.gov.au/pharmaceutical/Pages/cannabis-products.aspx
Email: MOH-PharmaceuticalServices@health.nsw.gov.au
Telephone: 02 9391 9944

NSW Cannabis Medicines Advisory Service:

Provides expert clinical guidance and support to NSW doctors and pharmacists
Website: https://www.health.nsw.gov.au/pharmaceutical/Pages/nsw-cmas.aspx
Email: HNELHD-CMAS@hnehealth.nsw.gov.au
Telephone: 02 4923 6200

Commonwealth Therapeutic Goods Administration:

For enquiries on Commonwealth Approval to access unregistered cannabis medicines
Website: https://www.tga.gov.au/access-medicinal-cannabis-products-1
Email: medicinal.cannabis@health.gov.au
Telephone: 02 6232 8866

Commonwealth Office of Drug Control:

For enquiries on the permission to import, cultivate, produce and manufacture cannabis
Website: https://www.odc.gov.au/medicinal-cannabis
Email: mcs@health.gov.au
Telephone: 02 6232 8433