Patient access to medicinal cannabis in South Australia

Discussion paper

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Government of South Australia
SA Health

Contents

Executive Summary

The South Australian Department for Health and Ageing (referred to throughout this discussion paper as "the Department") is committed to ensuring South Australian consumers have access to the optimal range of treatments and services to promote the best health outcomes.

There is public interest in the medicinal use of cannabis and cannabis-derived products and their use is subject to ongoing debate among health professionals and representative organisations. There is some clinical evidence for use of cannabis and derivatives in severe chronic conditions, and anecdotal reports of symptomatic benefit. To date, much of the use in these areas has involved illegal cultivation of cannabis or importation of cannabis-derived products that are not registered medicines. The available evidence supporting the efficacy of medicinal cannabis generally falls short of the standards required for approved medicines. Further research and development is progressing into the safety and efficacy of medicinal cannabis products, and to establish their role in clinical use.

To support further research and access for patients in who medicinal cannabis may offer some benefit, steps are being taken to facilitate availability of high quality medicinal cannabis products. The Australian Government has established a national licensing scheme under the *Narcotic Drugs Act 1967* for the cultivation, production and manufacture of cannabis for medicinal use which took effect on 30 October 2016. In addition, from 1 November 2016, the national medicines scheduling was changed to include cannabis for human therapeutic use as a Schedule 8 drug under certain criteria. South Australia adopts the national scheduling which means that authorised doctors can legally prescribe medicinal cannabis with relevant State and Commonwealth approvals.

Aligned with the national initiatives, the Department is developing a patient access pathway for medicinal cannabis. The proposed pathway takes account of the following in relation to medicinal cannabis products:

- they will be unapproved (unregistered) medicines;
- they will not have been evaluated for safety or efficacy by the Therapeutic Goods Administration (TGA);
- they will not be first line treatments.

The Department is proposing the indications for use under a patient access pathway be evidence-based and consistent with any nationally agreed consensus. In the current absence of a nationally agreed consensus it is proposed an expert panel of specialist medical practitioners is convened to provide clinical advice on a case by case basis.

The proposed pathway acknowledges the same high standards of safety and efficacy that apply to other prescription medicines in Australia should be applied to the emerging use of medicinal cannabis. Australia's obligations under international laws are also considered; specifically the obligation to establish a framework that prevents abuse and diversion of controlled drugs and to ensure the availability of such drugs for medical purposes.

The proposed pathway requires changes to controlled substances legislation to ensure national consistency towards safe and appropriate access. As the medicinal cannabis products that will be available will be unregistered medicines and should only be used when there has not been a satisfactory response to conventional treatments, the Department is proposing the following should apply:

- A medical practitioner would have to hold an authority granted by the Minister for the purposes of section 18A of the *Controlled Substances Act 1984* (a section 18A authority) before prescribing a medicinal cannabis product for a patient.
- Prescribing of medicinal cannabis products should be restricted to specialist medical practitioners.
- Section 18A authorities would only be granted for prescribing of medicinal cannabis for serious chronic illnesses that have not responded to conventional treatments.
- Current controls under the Controlled Substances (Poisons) Regulations 2011 about prescriptions for drugs of dependence, dispensing drugs of dependence on prescription, manufacture of drugs of dependence, administration and supply of drugs of dependence, record-keeping and destruction of drugs of dependence and the Code of Practice for the Storage and Transport of Drugs of Dependence would apply to medicinal cannabis products that are Schedule 8 drugs.

The proposed pathway uses established processes for assessing and authorising use of Schedule 8 drugs and promotes a timely and streamlined approval process.

It is expected the access pathway will be in place in 2017.

While legally produced medicinal cannabis products are currently not readily available in Australia, the national intention is that eventually there will be access to high quality Australian-grown and manufactured pharmaceutical products on prescription. It is anticipated that access to medicinal cannabis products produced to TGA standards may be possible in 2017.

It is important to note that while national initiatives enable appropriate, timely access to medicinal cannabis products for human therapeutic use, recreational use of cannabis remains illegal.

Interested parties are invited to provide comment about the proposed pathway for patient access to medicinal cannabis in South Australia, and the related legislative amendments. Responses to the questions posed in this discussion paper should be emailed by 31 January 2017, to Health.MedicinalCannabisConsultation@sa.gov.au

Background

The South Australian Department for Health and Ageing (referred to throughout this discussion paper as “the Department”) is committed to ensuring South Australian consumers have access to the optimal range of treatments and services to promote the best health outcomes.

In South Australia, access to medicinal cannabis may be considered for people with serious chronic illnesses that have not responded to conventional medical treatments under a proposed patient access pathway in 2017. This is in response to Australian Government initiatives as part of a national framework for patient access to cannabis for medicinal use. South Australia is participating in development of the national framework and considering how this can be implemented locally.

The purpose of this paper is to seek comment about the parameters that should apply to prescribing of medicinal cannabis under the proposed South Australian patient access pathway.

Schedule 8 drugs

Schedule 8 drugs are prescription medicines that have a recognised therapeutic need but also a higher risk of misuse, abuse and dependence. Other terms used in legislation for Schedule 8 drugs include ‘controlled drugs’ and ‘drugs of dependence’. These terms are used throughout this discussion paper.

Medicinal cannabis

Cannabis is a term that covers varieties of the *Cannabis* genus. The *Cannabis* plant produces a resin containing compounds called cannabinoids. Some cannabinoids possess psychoactive properties. Medicinal cannabis refers to cannabis derived pharmaceutical preparations (oils, capsules, tinctures and other forms) for human therapeutic use. Made from cannabis plant extracts, medicinal cannabis products contain specific active components in known amounts and mixtures, which maximise the therapeutic benefit and minimise side effects.

While a number of therapeutic uses of cannabis and its derivatives have been postulated there is still much controversy surrounding how to produce, supply and administer medicinal cannabis products. This is in part related to the complexity and number of compounds present; cannabis contains more than 60 cannabinoids, terpenoids and flavonoids that produce individual, interactive and entourage effects.

Medicines must have well defined and measurable ingredients that are consistent from one dosage unit to the next which allows clinicians and researchers to determine the optimum dose and frequency of dosing. This is one of the challenges when considering use of medicinal cannabis.

The medicinal cannabis products that will be available on prescription are those in which the dose and strength of the product can be controlled and standardised, making it safer for patients to use. Medicinal cannabis products meet the standards for cultivation and manufacture determined by the Commonwealth Department of Health (TGA and Office of

Drug Control (ODC)) and are not the same as crude cannabis products used for recreational purposes.

Use of cannabis as a medicine

Medicinal use of cannabis is subject to ongoing debate among health professionals and representative organisations. There is some clinical evidence and anecdotal reports of symptomatic benefit with use of medicinal cannabis in conditions such as severe drug-resistant epilepsy in children, multiple sclerosis, and in patients undergoing chemotherapy where conventional treatments have failed. To date, much of the use in these areas has involved illegal cultivation of cannabis or importation of cannabis-derived products that are not registered medicines.

A systematic review and meta-analysis of 79 clinical trials of cannabinoids was undertaken for the following indications; nausea and vomiting due to chemotherapy, appetite stimulation in HIV/AIDS, chronic pain, spasticity due to multiple sclerosis or paraplegia, depression, anxiety disorder, sleep disorder, psychosis, glaucoma and Tourette syndrome[1].

Information about the clinical trials used in the systematic review and other information on the evidence for medical of cannabis can be found in **Appendix I**.

Common adverse effects seen in the trials included dizziness, dry mouth, nausea, fatigue, somnolence, euphoria, vomiting, disorientation, drowsiness, confusion, loss of balance, and hallucinations.

Many of the cannabinoids used in these trials were pharmaceutical products containing nabilone, dronabinol and nabiximols. There are no products containing nabilone or dronabinol listed on the Australian Register of Therapeutic Goods (ARTG). Nabiximols (Sativex®) is listed on the ARTG but is not currently marketed in Australia.

There were limitations in relation to the trials of cannabinoids in the treatment of chemotherapy induced nausea and vomiting in that the comparator anti-emetics used in the trials did not reflect current anti-emetic regimens used for this indication.

There are already safe and effective registered medicines for the conditions for which medicinal cannabis might be considered. Although some studies suggest cannabis is associated with improvements in chemotherapy induced nausea and vomiting, weight gain in HIV infection, spasticity associated with multiple sclerosis and neuropathic pain, as yet there is no significant evidence that cannabis offers greater benefit than the registered medicines currently available to treat these conditions.

The American College of Pediatricians has concluded cannabis use is harmful to children and adolescents. The College has raised concerns about use of cannabis during pregnancy. The College urged extreme caution in legalising cannabis for medicinal use. The College does not support the availability of cannabis except in the context of well controlled scientific studies which demonstrate the medicinal benefit together with evidence based guidelines for optimal routes of delivery and dosing for specific medical conditions.[2]

[1] Whiting PF, Wolff RF, Deshpande S et al. Cannabinoids for medical use: A systematic review and meta-analysis. JAMA; 2015: 2456-2473.
[2] American College of Pediatricians April 2016 Marijuana use: detrimental to youth.

The Australian and New Zealand College of Anaesthetists Faculty of Pain Medicine statement on medicinal cannabis, with particular reference to its use in the management of patients with chronic non-cancer pain, indicates the Faculty of Pain Medicine does not endorse the use of cannabinoids in chronic non-cancer pain until such time as a clear therapeutic role is identified for them in the scientific literature. The statement indicates with the possible exception of pain and spasticity in multiple sclerosis (MS) there is little evidence for the effectiveness of cannabinoids in chronic non-cancer pain situations, whether or not the pain attracts the descriptor "neuropathic".[3]

Further research and development is progressing into the safety and efficacy of medicinal cannabis products and to establish their role in clinical use, including a program of clinical trials led by the New South Wales Government. South Australia has observer status on the Expert Panel convened in New South Wales to oversee the program of clinical trials. This program will provide data that will inform the safe and effective use of medicinal cannabis. More information about the trials can be found in **Appendix II**.

Unregistered medicines

The TGA regulates therapeutic goods, including prescription medicines to safeguard and enhance the health of the Australian community. Medicines imported into, supplied in and exported from Australia must be entered in the Australian Register of Therapeutic Goods (ARTG). Any medicine not on the ARTG is considered an unapproved or unregistered medicine.

Medicinal cannabis products are unregistered medicines (with the exception of Sativex® which is not currently marketed in Australia). They are not included on the ARTG and they have not been subject to the same quality, safety and efficacy testing required of other prescription medicines in Australia. Unregistered medicines, including unregistered medicinal cannabis products can be legally accessed with approval from the TGA. Unlike other prescription medicines, there are currently no clinical guidelines to support safe and appropriate use of unregistered medicinal cannabis products.

A small number of locally manufactured medicinal cannabis products may become available in 2017.

Information about the availability of medicinal cannabis products in Australia can be found in **Appendix III.**

[3] Australian and New Zealand College of Anaesthetists. Faculty of Pain Management. PM10 2015. Statement on "Medicinal Cannabis" with particular reference to its use in the management of patients with chronic non-cancer pain. Available at http://fpm.anzca.edu.au/documents/pm10-april-2015.pdf. Accessed 14 July 2016.

Australian Government initiatives

The Commonwealth has undertaken two initiatives as part of a national framework for patient access to cannabis for medicinal use.

The Australian Parliament passed amendments to the *Narcotic Drugs Act 1967* in February 2016. The changes to the *Narcotic Drugs Act 1967,* in operation from 30 October 2016, enable implementation of a national licensing scheme for the cultivation and production of cannabis for medicinal use, and manufacturing of products for medicinal use. This provides for a legal, domestic source of medicinal cannabis products which will only be available under medical supervision. The national licensing scheme will be tightly controlled and is wholly overseen by the Commonwealth Government. Cannabis grown for medicinal purposes, as well as the resulting product, will be subject to stringent security and quality control measures.

Domestic cultivation ensures sufficient supply for Australian patients and the production of a high quality product while also complying with international obligations. Information about the cultivation of cannabis for medicinal and related research purposes can be obtained from the Commonwealth Office of Drug Control.

The Commonwealth Department of Health has also made a change to the scheduling of cannabis for human therapeutic use. The change to the scheduling, in operation from 1 November 2016, means cannabis, when prepared or packed for human therapeutic use, is a Schedule 8 drug when:

- cultivated or produced, or in products manufactured , in accordance with the Narcotic Drugs Act 1967; and/or
- for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
- imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989;* and/or
- in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989.*[4]

The scheduling changes stipulate that medicinal cannabis will only be available from or on the prescription or order of, an authorised medical practitioner, and where the medical practitioner has been authorised by the appropriate State or Territory authority. This means that the medical practitioners that can prescribe or order cannabis will be limited to those specifically authorised by the Commonwealth and State (in South Australia, this means authorised under section 18A of the *Controlled Substances Act 1984*).

Commonwealth authorisation to supply an unregistered medicinal cannabis product (a product that is not included on ARTG) is via the Therapeutic Goods Administration Special Access Scheme or Authorised Prescriber Scheme; or where the product is used in a clinical trial, under Clinical Trials Notification (CTN) Scheme or Clinical Trials Exemption (CTX) Scheme. Approval is also required to import products that are not marketed in Australia.

Information about how other states and territories are implementing the Australian Government initiatives is available in **Appendix IV.**

[4] There are some exceptions to the Schedule 8 entry, refer to the public notice about the final decision about the scheduling of cannabis for complete details.

Proposed patient access in South Australia

The Department is developing a proposed pathway for patient access to medicinal cannabis in response to the Australian Government initiatives and is seeking feedback on the parameters that should apply to the pathway.

The proposed patient access pathway is aligned with the national intent and takes account of the limited clinical evidence and lack of a clear therapeutic role for medicinal cannabis. Regulatory amendments in South Australia are aligned with the national legal framework for access to medicinal cannabis. The pathway enables medical practitioners with relevant approvals to prescribe medicinal cannabis for patients with serious chronic illnesses that have not responded to, or failed conventional treatments.

The proposed pathway takes account of the following in relation to medicinal cannabis products:

- they will be unapproved medicines;
- they will not have been evaluated for safety or efficacy by the TGA;
- they will not be first line treatments.

The proposed pathway acknowledges there may be potential benefits for some patients and seeks to ensure medicinal cannabis products can be accessed safely while the evidence from clinical trials accumulates and a better understanding of their clinical role develops.

To access medicinal cannabis, relevant State and Commonwealth approvals are required, specifically:

- a section 18A authority granted under the South Australian *Controlled Substances Act 1984* to prescribe a Schedule 8 drug.
- approval from the Commonwealth TGA to supply an unregistered cannabis medicine.

TGA authorisation to supply an unregistered medicinal cannabis product (not included on the ARTG) is via the Special Access Scheme or Authorised Prescriber Scheme; or where the product is used in a clinical trial, under Clinical Trials Notification (CTN) Scheme or Clinical Trials Exemption (CTX) Scheme.

Currently medicinal cannabis products are not readily available in Australia and will likely need to be imported after obtaining approval from the TGA.

The TGA have indicated they will consider requests from appropriately qualified medical practitioners (generally specialists in the management of the disease being treated) for patients with chronic and serious medical conditions which have not responded to conventional treatments.

As part of the authority approval process in South Australia, applications will undergo clinical assessment by an expert advisory panel considering the following principles:

I. patient access is consistent with the intent of the national framework for patient access to cannabis for medicinal use

II. treatment is initiated by a specialist medical practitioner (specialist in the management of patients with the disease being treated)
III. treatment is only for serious, chronic medical conditions where other treatments have failed
IV. treatment should be evidence based acknowledging that evidence for safety and efficacy is accumulating
V. there must be informed consent of the patient
VI. judicious, safe and equitable use as per the National Medicines Policy.

Expert clinical advisory panel

The Department recommends that indications for use of medicinal cannabis are consistent with any nationally agreed consensus. In the current absence of a nationally agreed consensus and lack of a clear therapeutic role for medicinal cannabis, it is proposed an expert clinical panel be convened. The expert panel will provide clinical assessment of the prescribing and use of unregistered medicinal cannabis products in South Australia.

This approach is consistent with the regulatory requirements relating to the supply of medicinal cannabis products manufactured in Australia under the *Narcotic Drugs Act 1967*, and ensures that medicinal cannabis products are principally able to be accessed where appropriate oversight requirements are in place to safeguard public health.

The panel will assess the evidence and clinical information available and make clinical recommendations about applications for authority to prescribe medicinal cannabis, review outcomes of the use of medicinal cannabis and provide advice to the Department on related issues.

Applications for authority to prescribe medicinal cannabis will initially be assessed on a case by case basis, noting the types of conditions where clinical evidence suggests potential therapeutic benefits include:

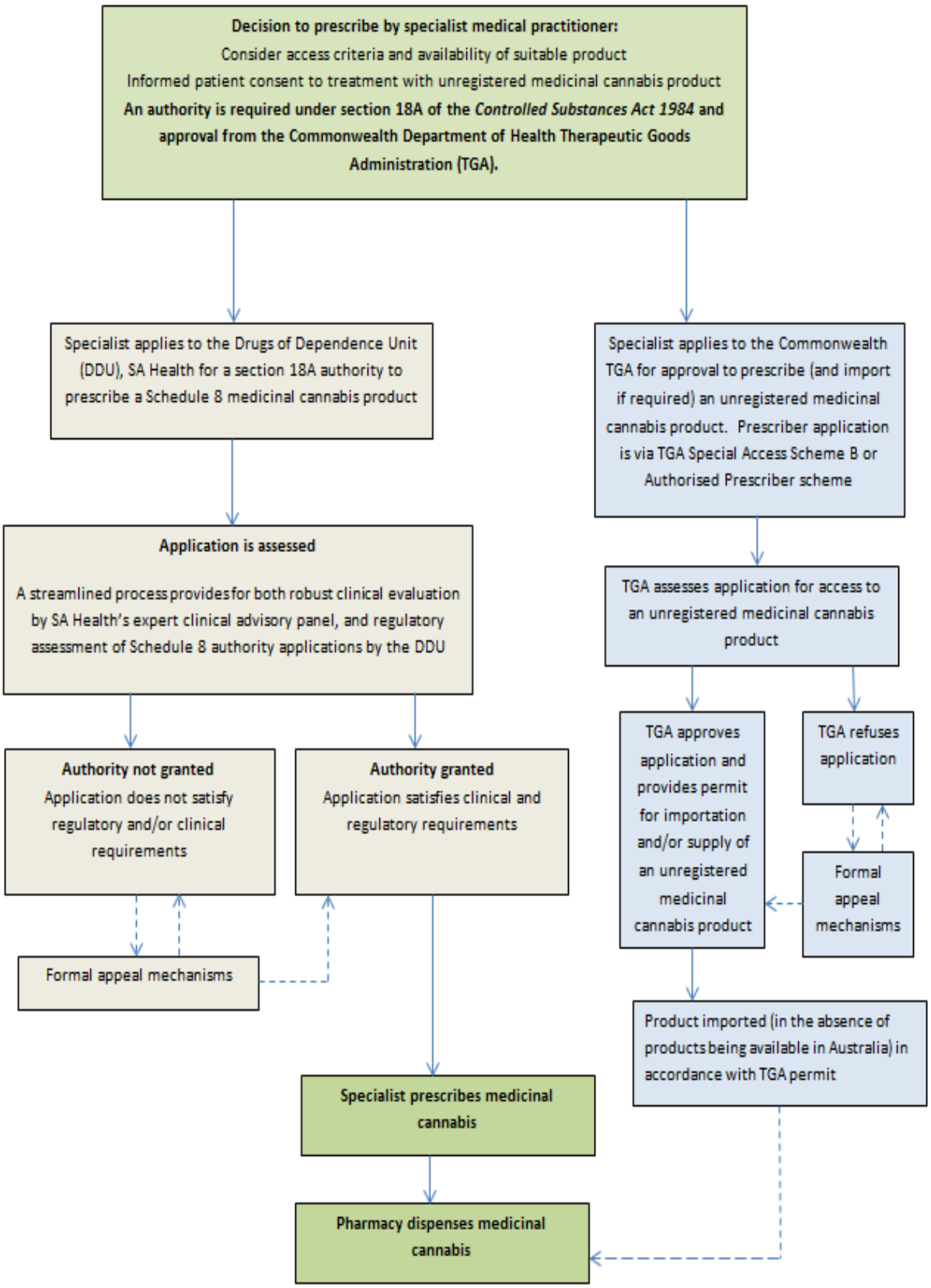
- severe seizures resulting from treatment resistant epilepsy
- palliative care related to terminal conditions
- severe nausea and vomiting or severe wasting resulting from cancer or HIV/AIDS (or their treatment)
- severe muscle spasms or pain resulting from multiple sclerosis.

It is proposed that as evidence emerges and clinical application is better understood, it may be appropriate, in order to streamline the authority approval process, that the expert advisory panel consider recommending guidelines for use.

The panel will include clinicians and experts in the relevant fields including pharmacology and medicines evaluation, paediatrics, cancer, neurology and palliative care, and consumer representation.

The panel will be an expert standing committee of the South Australian Medicines Advisory Committee (SAMAC), the peak medicines advisory committee of the Department for Health and Ageing to encourage the appropriate, equitable, safe and cost-effective use of medicines in South Australia.

Overview: Proposed Approval Process for Medicinal Cannabis in South Australia



Existing regulatory controls in South Australia

Current controls under the *Controlled Substances Act 1984* and Controlled Substances (Poisons) Regulations 2011[5] for prescribing, dispensing, manufacture, administration and supply of drugs of dependence; record keeping and destruction of drugs of dependence and the Code of Practice for the Storage and Transport of Drugs of Dependence, will apply to medicinal cannabis products that are Schedule 8 drugs.

Prescribing a drug of dependence

From 1 November 2016, cannabis for human therapeutic use is a Schedule 8 drug (drug of dependence), when:

- cultivated or produced, or in products manufactured , in accordance with the Narcotic Drugs Act 1967; and/or
- for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
- imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989;* and/or
- in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989.*

To prescribe medicinal cannabis in South Australia, the prescriber must be authorised under section 18A of the *Controlled Substance Act 1984,* and by the Commonwealth Department of Health, TGA.

Commonwealth authorisation is under the TGA's Special Access Scheme or Authorised Prescriber Scheme, or under the Clinical Trials Notification (CTN) Scheme or the Clinical Trials Exemption (CTX) Scheme.

In South Australia, section 18A(1) of the *Controlled Substances Act 1984*[5] specifies the requirements a registered health practitioner must meet if he or she prescribes or supplies a drug of dependence.

A registered health practitioner must not prescribe any drug of dependence for, or supply any drug of dependence to—

(a) a person for regular use by the person during a period exceeding two months, or during a period that, together with any other period for which a drug of dependence has, to the practitioner's knowledge, been prescribed or supplied by a registered health practitioner, would result in drugs of dependence being regularly used by the person during a period exceeding two months; or

(b) a person who the practitioner knows or has reasonable cause to believe is dependent on drugs,

unless the person prescribes or supplies the drug in accordance with an authority granted by the Minister under this section (a section 18A authority) or in circumstances that are exempted from this subsection by the regulations.

[5] The *Controlled Substances Act 1984* and Controlled Substances (Poisons) Regulations 2011 is available at: https://www.legislation.sa.gov.au/LZ/C/A/CONTROLLED%20SUBSTANCES%20ACT%201984/CURRENT/1984.52.UN.PDF.

Regulation 22(2) of the Controlled Substances (Poisons) Regulations 2011 specifies a registered health practitioner who is authorised to prescribe or supply a drug of dependence is exempt from the requirement to hold a section 18A authority in relation to prescribing or supplying a drug of dependence for a person in respect of whom a section 18A authority does not exist if—

(a) The drug (not being dextromoramide or pethidine) is for use by a person aged 70 years or more; or

(b) The drug (not being dextromoramide or pethidine) is for use by a person whose life expectancy is reasonably believed by the registered health practitioner principally responsible for the treatment of the person, to be less than 12 months and—

  (i) the registered health practitioner has informed the Minister of the person's name and address, date of birth and the nature of the condition for which the drug is prescribed; and

  (ii) the prescription for the drug is endorsed either "Notified Palliative Care Patient" or "NPCP"; or

(c) The drug is for use by a person who is receiving treatment in a hospital or correctional institution and the duration of treatment of the person with the drug while the person is in the hospital or correctional institution does not exceed 14 days; or

(d) The drug is for use by a person who is being discharged from a hospital following treatment in hospital and the duration of the treatment of the person with the drug after discharge does not exceed 14 days.

Requirements to hold a section 18A authority to prescribe or supply medicinal cannabis for a person

Legislative controls on the prescribing of Schedule 8 drugs (drugs of dependence) exist to protect patients, health professionals and the wider community from the known harms and risks of these. Legislation allows for timely access in circumstances where use of registered Schedule 8 drugs without a section 18A authority is appropriate and necessary, for example in the treatment of acute pain where short term use of opioid medication may be required.

At present there is one medicinal cannabis product (Sativex®) that is a registered medicine in Australia (it is not marketed in Australia). The current exemptions under regulation 22(2) apply to prescribing or supply of Sativex®.

It may be appropriate for the usual conditions and exemptions that apply to the prescribing and supply of Schedule 8 drugs to continue to apply to prescribing or supply of *registered* medicinal cannabis products.

Proposed regulatory amendments for medicinal cannabis in South Australia

As in a number of other jurisdictions, the proposed patient access pathway in South Australia requires changes to controlled substances legislation to ensure national consistency towards safe and appropriate access. As the medicinal cannabis products that will be available will be unregistered medicines and should only be used when there has not been a satisfactory response to conventional treatments, the Department is proposing the following should apply:

- A medical practitioner would have to hold an authority granted by the Minister for the purposes of section 18A of the *Controlled Substances Act 1984* (a section 18A authority) before prescribing a medicinal cannabis product for a patient.
- Prescribing of medicinal cannabis products should be restricted to specialist medical practitioners.
- Section 18A authorities would only be granted for prescribing of medicinal cannabis for serious chronic illnesses that have not responded to conventional treatment.
- Current controls under the Controlled Substances (Poisons) Regulations 2011 about prescriptions for drugs of dependence, dispensing drugs of dependence on prescription, manufacture of drugs of dependence, administration and supply of drugs of dependence, record-keeping and destruction of drugs of dependence and the Code of Practice for the Storage and Transport of Drugs of Dependence, would apply to medicinal cannabis products that are drugs of dependence.

The following options and their risks and benefits have been considered:

Option 1: Status quo – require a medical practitioner to hold a section 18A authority to prescribe or supply a Schedule 8 medicinal cannabis product after two months of treatment.

Under this option, the requirements for prescribing unregistered medicinal cannabis products would be the same as those currently in place for other Schedule 8 drugs that are registered medicines. That is:

A registered medical practitioner would only have to hold a section 18A authority to prescribe or supply a Schedule 8 medicinal cannabis product after two months of treatment, unless the person is dependent on drugs or the person has already been treated with a drug of dependence (for example morphine for pain) during a period exceeding two months.

The current exemptions from the requirement to hold a section 18A authority if the product is prescribed or supplied to a Notified Palliative Care Patient or a person aged 70 years or more, would also apply to medicinal cannabis.

Under this option, there would be less administrative burden on a medical practitioner who wanted to trial a medicinal cannabis product in a patient.

The risks for patients and community public health are not adequately managed under this option; the greatest being that the quality, safety and efficacy of these medicinal cannabis products have not been verified to the standards applicable to other prescription medicines.

Under this option it may not be possible to provide timely and appropriate oversight for the use of medicinal cannabis, particularly if there is inappropriate prescribing or diversion of cannabis products.

This option does not take account of the national scheduling for medicinal cannabis products that includes the requirement that these only be available from or on the prescription or order of a medical practitioner authorised by the relevant authority (in South Australia, a section 18A authority granted under the *Controlled Substances Act 1984*). This is also inconsistent with the general approach taken by other state jurisdictions and does not afford patients with the opportunity for timely expert clinical oversight under the proposed patient access pathway.

Option 1 is not the preferred option.

Option 2: Require a medical practitioner to hold a section 18A authority before prescribing or supplying an unregistered Schedule 8 medicinal cannabis product, with current exemptions maintained for persons aged 70 years or more or a Notified Palliative Care Patient.

Under this option a medical practitioner would not be able to prescribe medicinal cannabis for two months without first holding a section 18A authority, except for persons aged 70 years or more or a Notified Palliative Care Patient.

Mandating a medical practitioner hold a section 18A authority before prescribing or supplying an unregistered Schedule 8 medicinal cannabis product is consistent with the intent of the national scheduling.

The medicinal cannabis products will not be registered medicines and should only be used if conventional treatment options have not been effective or have resulted in side effects that are intolerable for the patient.

There may be pressure on general practitioners to prescribe medicinal cannabis without an adequate trial of other treatment options. Having a requirement for the prescriber to hold a section 18A authority could help ease any such pressure on prescribers.

The Department would have more timely information about prescribing and supply of medicinal cannabis products and would be able to ensure expert clinical review, and should be able to reduce the likelihood of inappropriate prescribing or supply. Appropriate conditions could be applied to the supply of medicinal cannabis products at the time treatment is initiated minimising risk of misuse or abuse of the products.

Under this option, the current exemptions from the requirement to hold a section 18A authority if medicinal cannabis is prescribed or supplied to a Notified Palliative Care Patient or a person aged 70 years or more would still apply to medicinal cannabis. These existing exemptions for registered Schedule 8 drugs are inconsistent with the intent of the national scheduling for medicinal cannabis. The exemptions may also be inconsistent with the described principles of safe treatment with unregistered medicinal cannabis products and would not afford these patient groups the opportunity for timely, expert clinical assessment that would be provided by the expert advisory panel under the proposed patient access pathway.

It is unclear what risk of diversion and misuse would apply to use of medicinal cannabis products. The risk of diversion and misuse in Notified Palliative Care Patients and patients aged 70 years and over is unknown.

There may be concerns about the potential for delay in patients being able to access medicinal cannabis if the prescriber needs to hold an authority before prescribing. As approvals from the TGA would also be required and (currently) a product imported, there is unlikely to be any additional delay by requiring a section18A approval prior to commencing treatment with a medicinal cannabis product. There are other products available to manage these conditions in the interim to authority being granted.

There may be concerns about additional costs for patients to consult a specialist medical practitioner. However, most patients suffering the conditions for which medicinal cannabis might be considered would already be under the management of a specialist medical practitioner.

Option 2 is not the preferred option.

Option 3: Require a medical practitioner to hold a section 18A authority before prescribing or supplying an unregistered Schedule 8 medicinal cannabis product, without exemptions for persons aged over 70 years or for Notified Palliative Care Patients.

Mandating a medical practitioner holds a section 18A authority before prescribing or supplying an unregistered Schedule 8 medicinal cannabis product has benefits and risks that apply to option 2 as stated above.

This option would better reflect the national intent that unregistered medicinal cannabis products only be used if conventional treatments have been ineffective or have resulted in intolerable side effects for the patient. This approach is also consistent with that being taken by other state jurisdictions (including Victoria, Tasmania, New South Wales and Western Australia) and provides access to medicinal cannabis in circumstances where there are appropriate oversight requirements in place to safeguard public health and patient safety considering their status as unregistered medicines.

The Department would have more timely information about all prescribing and supply of medicinal cannabis products and should be able to reduce the likelihood of inappropriate prescribing or supply. Appropriate conditions could be applied to the supply of medicinal cannabis products at the time treatment is initiated minimising risk of misuse, abuse or diversion of the products.

This option is likely to result in the most appropriate use of unregistered medicinal cannabis products.

This option affords all patient groups the opportunity for timely, expert clinical assessment that would be provided by the expert advisory panel under the proposed patient access pathway and is likely to result in the safest use of medicinal cannabis products in South Australia.

It is acknowledged that this option will require prescribers to obtain an authority to treat Notified Palliative Care Patients and those over 70 years of age with medicinal cannabis in the first instance whereas for other registered Schedule 8 drugs, an authority is not required.

This may raise concerns about the potential for delay in patients being able to access medicinal cannabis if the prescriber needs to hold an authority before prescribing. As approvals from the TGA would also be required and (currently) a product imported, there is unlikely to be any additional delay through the requirement for a section18A approval prior to commencing treatment with a medicinal cannabis product. There are other products available to manage these conditions in the interim to an authority being granted.

Under the proposed access pathway, access will be timely and considered, for all patients.

Option 3 is the preferred option.

Questions

1. Should a medical practitioner be required to hold a section 18A authority before prescribing an unregistered schedule 8 medicinal cannabis product?
2. Should a medical practitioner be required to hold a section 18A authority before prescribing an unregistered schedule 8 medicinal cannabis product for patients over 70 years of age and Notified Palliative Care Patients?

Other considerations

Under the proposed pathway, authorities will only be granted to specialist medical practitioners (specialist in the management of patients with the disease being treated). This may have implications for patients seeking to access treatment with medicinal cannabis when considering the practicalities of consulting a specialist medical practitioner. However it is expected that patients suffering complex medical conditions, for which use of medicinal cannabis might be considered, would already be under the management of a specialist medical practitioner. There may be consideration about whether it would be appropriate for a general practitioner to be granted a section 18A authority to continue prescribing a medicinal cannabis product where the treatment is initiated and overseen by a specialist medical practitioner.

The prescriber should also ensure the patient is fully informed about the nature of treatment with a medicinal cannabis product that is not included on the ARTG, or is used for an off-label indication. The prescriber should also inform the patient that current drug-driving laws apply to the medicinal use of cannabis.

Questions

3. Should there be consideration of a provision for a general practitioner to be able to hold a section 18A authority to continue treatment initiated and overseen by a specialist medical practitioner?

Other existing regulatory controls that apply to Schedule 8 medicinal cannabis in South Australia

Requirements under the Controlled Substances (Poisons) Regulations 2011

There are requirements under the Controlled Substances (Poisons) Regulations 2011 relevant to prescriptions and orders for drugs of dependence for human use. These include requirements about:

- how prescriptions for drugs of dependence are given, the information that must be included on the prescription and about dispensing drugs of dependence on prescription (r33, 34 and 35);
- special restrictions on prescription or supply of drugs of dependence by registered health practitioners and veterinary surgeons (r37);
- the records that must be kept by a manufacturer of a drug of dependence (r39);
- the records that must be kept when a drug of dependence is sold or supplied by a supplier (for example a pharmacist) (r40);
- the records that must be kept by a supplier when he or she receives a drug of dependence (r41);
- the records that must be kept when a drug of dependence is administered or supplied by a registered health practitioner who is not a pharmacist (r42);
- additional requirements for the administration of a drug of dependence in a health service facility (r44);
- destruction of a drug of dependence (r45);
- retention of records and keeping a drugs of dependence register (r49).
- Information about the key requirements can be found in Appendix V.

It is unclear at present whether there will be a greater risk of diversion or misuse of medicinal cannabis products when compared with other Schedule 8 poisons such as morphine and oxycodone. It is likely there will be limited access to products in the immediate future (until such time as medicinal cannabis products are produced and manufactured in Australia) and the cost of products may be significant.

It is proposed that:

- the current requirements for supply of drugs of dependence by pharmacists on prescription and for recording supply are appropriate for supply of medicinal cannabis.
- the current requirements for administration or supply by a registered health practitioner are appropriate for administration or supply of medicinal cannabis to a person, including administration in a health service facility.

Questions

4. Should there be different requirements (compared with the usual requirements that apply to sale or supply of drugs of dependence) for pharmacists in relation to dispensing medicinal cannabis on prescription or supplying medicinal cannabis on order and recording such supply? If so, please detail what requirements should apply.
5. Should there be different requirements (compared with the usual requirements that apply to administration and supply of drugs of dependence) for recording administration or supply of medicinal cannabis by a registered health practitioner, including when the drug is administered in a health service facility? If so, please detail what requirements should apply.

Destruction of a Schedule 8 drug of dependence

Regulation 45 specifies the requirements for destruction of a drug of dependence. The destruction must be witnessed by a specified class of person and information recorded about what has been destroyed and the names and signatures of the person and the witness to the destruction.

It is unclear at present whether the risk of diversion and misuse will be similar to that for other drugs of dependence. It is proposed the usual requirements that apply to the destruction of a drug of dependence would apply to the destruction of a medicinal cannabis product. There may need to be consideration of the most appropriate method for destruction of a medicinal cannabis product in the form of plant material.

Question

6. Should there be different requirements for the destruction of medicinal cannabis products? If so, what requirements should apply?

Storage and transport of drugs of dependence

The Department's Code of Practice for the Storage and Transport of Drugs of Dependence (the Code) specifies the level of security required for the storage and transport of drugs of dependence. The level of security required varies according to the type of facility (e.g. pharmacy, ward in a hospital, general practice), the number of doses of drugs of dependence stored and the extent of monitoring of the drug cabinet, safe or strongroom.

The Code also specifies who may access the drugs of dependence from the drug cabinet, safe or strongroom. Only registered health practitioners, veterinary surgeons, permit or licence holders who are permitted under the *Controlled Substances Act 1984* to possess drugs of dependence and are working at the premises on which a drug cabinet, safe or strong room is located are permitted to access the drugs of dependence.

The Code is currently being updated to:

- permit rail transport of drugs of dependence with the same requirements applying to rail transport as apply to transporting large quantities of drugs of dependence by road or air;
- provide for the Manager, Drugs of Dependence Unit to approve alternative forms of storage for pharmacies, for example, to take account of use of new technologies such as dispensing robots;
- require that the packaging of drugs of dependence for transport must comply with all the requirements under clause 5.1 of the Code;
- permit a veterinary nurse, under the direction and supervision of a veterinary surgeon, and acting in the ordinary course of his or her profession to access drugs of dependence.

There will also be a comprehensive review of the Code in the near future. It is proposed, in the interim, that the requirements for the storage and transport of drugs of dependence are appropriate for ensuring the security of medicinal cannabis products.

More information about requirements under South Australian controlled substances legislation is available in **Appendix V**.

Question
7. Are there any factors unique to medicinal cannabis products that need to be taken into account in relation to the storage and transport requirements for these products? If so, please provide details of any relevant factors.

Proposed Medicinal Cannabis Patient Access Pathway in South Australia - Summary

- A medical practitioner must hold a section 18A authority granted under section 18A of the *Controlled Substances Act 1984* before prescribing medicinal cannabis for a patient.

- Authority to prescribe medicinal cannabis products will be restricted to specialist medical practitioners.

- Authority will only be granted to prescribe medicinal cannabis for patients with serious chronic illnesses that have not responded to conventional treatments.

- Authority will only be granted for products made under the Commonwealth's licensing scheme or imported with approval from the Commonwealth Department of Health, TGA.

- SA Health will establish an expert clinical advisory panel to make recommendations about applications for authority to prescribe medicinal cannabis, review outcomes of the use of medicinal cannabis in South Australia and provide advice to the Department of Health and Ageing on issues related to medicinal cannabis.

- Current controls under the Controlled Substances (Poisons) Regulations 2011 about prescribing drugs of dependence, dispensing drugs of dependence on prescription, manufacture of drugs of dependence[6], administration and supply of drugs of dependence, record-keeping and destruction of drugs of dependence, and the Code of Practice for the Storage and Transport of Drugs of Dependence will apply to medicinal cannabis products that are drugs of dependence.

- To prescribe an unregistered Schedule 8 medicinal cannabis product in South Australia, the prescriber must be also be authorised by the Commonwealth Department of Health, TGA.

There may be other matters that may apply to the patient access pathway and controlled substances legislation after consideration of feedback from consultation.

Question	
8.	Are there any other matters that need to be considered in developing the access pathway? If so, please provide details.

[6] The person would also have to comply with the requirements under the *Narcotic Drugs Act 1967* (Cth).

Appendix I: Whiting PF, Wolff RF, Deshpande S et al. Cannabinoids for medical use: A systematic review and meta-analysis[7]

Whiting et al undertook a systematic review and meta-analysis of 79 randomized clinical trials that compared cannabinoids with usual care, placebo or no treatment in the following indications; nausea and vomiting due to chemotherapy, appetite stimulation in HIV/AIDS, chronic pain, spasticity due to multiple sclerosis (MS) or paraplegia, depression, anxiety disorder, sleep disorder, psychosis, intraocular pressure in glaucoma or Tourette syndrome.

If no randomized clinical trials were available for a particular indication or outcome (for example long term adverse effects such as cancer, psychosis, depression or suicide), nonrandomized studies including uncontrolled studies (such as case series) with at least 25 patients were eligible.

Thirty four studies were parallel group trials (4436 participants) and 45 were crossover trials (2026 participants).

Four trials (5%) were judged at low risk of bias, fifty-five (70%) trials were at high risk and 20 (25%) were at unclear risk of bias.

A range of cannabinoids were evaluated and compared with various different active comparators or placebos; most active comparators were included for the nausea and vomiting indication.

They concluded there was:

- moderate quality evidence to support the use of cannabinoids for the treatment of chronic pain and spasticity;
- low quality evidence suggesting that cannabinoids were associated with improvements in nausea and vomiting due to chemotherapy, weight gain in HIV infection, sleep disorders and Tourette syndrome.

Common adverse effects seen in the trials included dizziness, dry mouth, nausea, fatigue, somnolence, euphoria, vomiting, disorientation, drowsiness, confusion, loss of balance, and hallucinations.

Many of the cannabinoids used in these trials were pharmaceutical products containing nabilone, dronabinol and nabiximols. There are no products containing nabilone or dronabinol listed on the ARTG. Nabiximols (Sativex®) is listed on the ARTG but is not currently marketed in Australia.[8]

There were limitations in relation to the trials of cannabinoids in the treatment of chemotherapy induced nausea and vomiting in that the comparator anti-emetics used in the trials did not reflect current anti-emetic regimens used for this indication.

[7] JAMA 2015; 313 (24): 2456-2473.
[8] Whiting PF, Wolff RF, Deshpande S et al. Cannabinoids for medical use: A systematic review and meta-analysis. JAMA; 2015: 2456-2473.

Chronic pain

Chronic pain was assessed in 28 studies (63 reports; 2454 participants). Thirteen studies assessed nabiximols[9], four assessed smoked tetrahydrocannabinol (THC), five assessed nabilone[10], three assessed oromucosal THC spray, two assessed dronabinol[11], one assessed vaporized cannabis, one assessed ajulemic acid[12] capsules and one assessed oral THC. One trial compared nabilone with amitriptyline, all the other studies were placebo controlled. One of the studies evaluated nabilone as an adjunctive treatment to gabapentin.

The conditions causing the chronic pain varied between the studies and included neuropathic pain (central, peripheral or not specified; 12 studies), cancer pain (three studies), diabetic peripheral neuropathy (three studies), fibromyalgia (two studies), HIV associated sensory neuropathy (two studies) and one study for each of the following: refractory pain due to MS or other neurological conditions, rheumatoid arthritis, non-cancer pain (nociceptive and neuropathic), central pain (not specified further), musculoskeletal problems, and chemotherapy-induced pain.

Two of the studies were at low risk of bias, nine were at unclear risk and seventeen were at high risk of bias.

Studies generally suggested improvements in pain measures with cannabinoids but these did not reach statistical significance in most individual studies.

The average number of patients who reported a reduction in pain of at least 30% was greater with cannabinoids than with placebo (OR, 1.41 [95% CI, 0.99- 2.00]; eight trials). One trial assessed smoked THC and reported the greatest beneficial effect (OR, 3.43 [95% CI, 1.03-11.48]) and seven trials assessed nabiximols. Pain conditions evaluated in these trials were neuropathic pain (six trials) and cancer pain (two trials) with no clear differences between pain conditions.

Nabiximols were also associated with a greater average reduction in the Numerical Rating Scale (NRS; 0-10 scale) assessment of pain (weighted mean difference (WMD), -0.46 [95% CI, -0.80 to -0.11]; six trials), brief pain inventory short form, severity composite index (WMD, -0.17 [95% CI, -0.50 to 0.16]; three trials), neuropathic pain scale (WMD, -3.89 [95% CI, -7.32 to -0.47]; five trials), and the proportion of patients reporting improvement on a global impression of change score (OR, 2.08 [95% CI, 1.21 to 3.59]; six trials) compared with placebo. There was some evidence to support this based on continuous data but this was

[9] Nabiximols (Sativex) was included on the Australian Register of Therapeutic Goods on 26 November 2012 for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. Sativex is not marketed in Australia. It contains a plant derived extract that contains delta-9 THC and cannabidiol in approximately equal proportions.

[10] Nabilone (Cesamet) is not marketed in Australia. Nabilone was approved by the FDA in 1985 for the treatment of chemotherapy induced nausea and vomiting that has not responded to conventional antiemetics. Nabilone is a synthetic cannabinoid derivative that mimics the effects of THC.

[11] Dronabinol (Marinol) is not marketed in Australia. Dronabinol is a synthetic pure isomer of delta-9 THC. Dronabinol was approved by the FDA in 1985 for the treatment of chemotherapy induced nausea and vomiting that has not responded to conventional antiemetics.

[12] Ajulemic acid is a synthetic non-psychoactive derivative of the THC metabolite 11-nor-9-carboxy-THC.

not consistent across trials. There was no difference in average quality of life scores as measured by the EQ-5D health status index between nabiximols and placebo. Two of the studies included in the meta-analysis for the NRS assessed patients with cancer pain; all other studies assessed patients with neuropathic pain. There were no clear differences based on cause of pain in the meta-analysis of NRS. Sensitivity analyses that included crossover trials showed results consistent with those based on parallel group trials alone.

Spasticity due to MS or paraplegia

Fourteen studies (33 reports, 2280 participants) assessed spasticity due to MS or paraplegia. Eleven studies (2138 participants) included patients with MS and three studies (142 participants) included patients with paraplegia caused by spinal injury.

Six studies assessed nabiximols, three assessed dronabinol, one assessed nabilone, four assessed THC/cannabidiol (two of these also assessed dronabinol), one assessed ECP002A[13] and one assessed smoked THC. All studies included a placebo control group; none included an active comparator.

Two studies were at low risk of bias, five were at unclear risk of bias and seven were at high risk of bias.

The studies generally suggested cannabinoids were associated with improvements in spasticity but this failed to reach statistical significance in most studies.

There were no clear differences based on the type of cannabinoid.

Nausea and vomiting due to chemotherapy

Nausea and vomiting due to chemotherapy was assessed in 28 studies (37 reports, 1772 participants).

Fourteen studies assessed nabilone, three assessed dronabinol, one assessed nabiximols, four assessed levonantradol[14] and six assessed tetrahydrocannabinol (THC). Two studies also included a combination therapy group of dronabinol with ondansetron or prochlorperazine. Eight studies included a placebo control, three of these also included an active comparator, and 20 studies included only an active comparator. The most common active comparators were prochlorperazine (15 studies), chlorpromazine (two studies) and domperidone (two studies). The other active comparators (alizapride, hydroxyzine, metoclopramide and ondansetron) were evaluated in single studies.

Twenty-three of the studies were at high risk of bias and five studies were at unclear risk of bias.

All studies suggested a greater benefit of cannabinoids compared with both active comparators and placebo, but these did not reach statistical significance in all studies. The average number of patients showing a complete nausea and vomiting response was greater with cannabinoids (dronabinol or nabiximols) than placebo (OR, 3.82 [95% CI, 1.55-9.42]; three trials).

[13] ECP002A is pure natural delta-9 THC. It does not have marketing authorisation in Australia, the USA or the European Union.
[14] Levonantradol is not marketed in Australia. It is a synthetic derivative of dronabinol.

Appetite stimulation in HIV/AIDS Infection

Appetite stimulation in HIV/AIDS was assessed in four studies (four reports, 255 participants).

All studies assessed dronabinol, three compared with placebo and one compared with megestrol acetate.

All studies were at high risk of bias.

There was some evidence that dronabinol was associated with an increase in weight when compared with placebo. More limited evidence suggested it may also be associated with increased appetite, greater percentage of body fat, reduced nausea, and improved functional status. These outcomes were mostly assessed in single studies and associations failed to reach statistical significance.

The trial that evaluated cannabis and dronabinol found significantly greater weight gain with both forms of cannabinoid when compared with placebo.

The active comparator trial found that megestrol acetate was associated with greater weight gain than dronabinol and combining megestrol acetate with dronabinol did not lead to additional weight gain.

Sleep disorder

Two studies (five reports, 54 participants) evaluated nabilone for the treatment of sleep problems. One was a parallel group trial judged at high risk of bias. This trial reported a greater benefit of nabilone compared with placebo on the sleep apnoea/hypopnoea index (mean difference from baseline, -19.64; *P* value =0.02). The other was a crossover trial judged at low risk of bias in patients with fibromyalgia and compared nabilone with amitriptyline. This study suggested nabilone was associated with improvements in insomnia and with greater sleep restfulness.

Nineteen placebo controlled studies included for other indications (chronic pain and MS) also evaluated sleep as an outcome. Thirteen studies assessed nabiximols, one assessed nabilone, one assessed dronabinol, two assessed THC/CBD capsules and two assessed smoked THC (one at various doses). Two of the studies that assessed nabiximols also assessed oral THC and the trial of dronabinol also assessed oral THC/CBD. There was some evidence that cannabinoids may improve sleep in these patient groups. Cannabinoids (mainly nabiximols) were associated with a greater average improvement in sleep quality and sleep disturbance. One trial assessed THC/CBD, all the others assessed nabiximols, results were similar for both cannabinoids.

Movement disorders due to Tourette syndrome

Two small placebo controlled studies (4 reports, 36 participants) suggested THC capsules may be associated with a significant improvement in tic severity in patients with Tourette syndrome.

Other information

Other conditions where use of medicinal cannabis has been suggested include rheumatological conditions, inflammatory bowel disease, refractory epilepsy, Huntington's Chorea, Parkinson's Disease, Post-Traumatic Stress Disorder and cancer.

There have been anecdotal reports of symptomatic benefit with use of medicinal cannabis in conditions such as severe drug-resistant epilepsy. The GW Pharma product Epidiolex (cannabidiol) and an Insys Therapeutics cannabidiol product are currently in Phase III trials. The early results from the trials of Epidiolex in Dravet Syndrome and Lennox-Gastaut Syndrome have shown some promising results.

Given that cannabis has so many constituents the results of studies with individual cannabinoids such as tetrahydrocannabinol (THC) or cannabidiol cannot be extrapolated to cannabis products that contain more than one cannabinoid and vice versa. The results from studies with particular dose forms (e.g. inhaled or smoked) may not be able to be extrapolated to other dose forms such as tablets. The relative benefits of prescribing plant-derived versus synthetic cannabinoids need to be determined.

Although there are data for some cannabinoids that are registered for marketing overseas (nabilone and dronabinol) or nabiximols, in general, appropriate starting doses and likely toxic doses for other cannabinoids and in patient groups with different pharmacokinetics are not known.

Data on central nervous system toxicity or other toxicity, particularly for children or adolescents or in end of life patients with significant neuropsychiatric changes and who are already taking multiple medicines, are still to be determined.

The effects of repeated exposure that could occur with medicinal use of cannabis need further study. Approximately 1 in 10 adult users of cannabis develops dependence and this number is even higher in adolescents. Tolerance and dependence with accompanying down regulation and desensitisation of type 1 cannabinoid receptors occur with repeated exposure. A distinct withdrawal syndrome is also recognised.[15]

There are limited data about the adverse effects of medicinal cannabis and the interaction between medicinal cannabis and other medicines patients may be consuming.

The evidence supporting the efficacy of medicinal cannabis generally falls short of the standards required for approval of medicines. There are already safe and effective registered medicines for the conditions for which patients are requesting access to cannabis. Although some studies suggest cannabis is associated with improvements in chemotherapy induced nausea and vomiting, weight gain in HIV infection, spasticity associated with multiple sclerosis and neuropathic pain, as yet there is no significant evidence that cannabis is superior to the registered medicines currently available to treat these conditions.

The American College of Pediatricians has concluded cannabis use is harmful to children and adolescents. The College has raised concerns about use of cannabis during pregnancy. The College urged extreme caution in legalizing cannabis for medicinal use. The College does not support the availability of cannabis except in the context of well controlled scientific studies which demonstrate the medicinal benefit together with evidence based guidelines for optimal routes of delivery and dosing for specific medical conditions.[16]

The Australian and New Zealand College of Anaesthetists Faculty of Pain Medicine Statement on “medicinal cannabis” with particular reference to its use in the management of patients with chronic non-cancer pain indicates the Faculty of Pain Medicine does not endorse the use of cannabinoids in chronic non-cancer pain until such time as a clear therapeutic role is identified for them in the scientific literature. The statement indicates with

[15] D’Souza DC and Rangannathan M. Medical marijuana; Is the cart before the horse? JAMA 2015; 313: 2431-2432.
[16] American College of Pediatricians April 2016 Marijuana use: detrimental to youth.

the possible exception of pain and spasticity in Multiple Sclerosis (MS) there is little evidence for the effectiveness of cannabinoids in chronic non-cancer pain situations, whether or not the pain attracts the descriptor “neuropathic”.[17]

[17] Australian and New Zealand College of Anaesthetists. Faculty of Pain Management. PM10 2015. Statement on “Medicinal Cannabis” with particular reference to its use in the management of patients with chronic non-cancer pain. Available at http://fpm.anzca.edu.au/documents/pm10-april-2015.pdf. Accessed 14 July 2016.

Appendix II: New South Wales led program of clinical trials

In December 2014 the New South Wales Government announced a program of clinical trials with funding of up to $9 million over the next five years[18]. The program aims to build the evidence on cannabis and cannabis products in providing relief for patients suffering a range of difficult to treat and debilitating or terminal illnesses.

The New South Wales Ministry of Health is administering clinical trials in the areas of:

- Adults with terminal illness, focusing on improving quality of life, and symptoms such as pain, nausea and vomiting.
- Adults with chemotherapy-induced nausea and vomiting, where standard treatment is ineffective.

The first trial in adults will evaluate vaporised leaf cannabis and a pharmaceutical product in alleviating symptoms in terminally ill patients. The first part of the trial has started and is being conducted with approximately 30 adults at the Calvary Mater Hospital in Newcastle.[19] The study will provide safety and dose finding data for vaporised botanical leaf cannabis and within a tight dose range for patients with cancer-related cachexia.[20]

There will be a trial of a cannabis-derived tablet that contains tetrahydrocannabinol and cannabidiol in about 330 patients suffering chemotherapy associated nausea and vomiting who have not responded to the standard treatments.[21] The tablet is manufactured by the Canadian company, Tilray.

There will be New South Wales based trials in children with severe drug-resistant epilepsy, coordinated through the Sydney Children's Hospitals Network. The trials will use cannabis-derived products manufactured and supplied by GW Pharmaceuticals that contain cannabidivarin and cannabidiol.[22] Cannabidivarin and cannabidiol do not have the psychoactive effects associated with use of cannabis plant material that contains high levels of THC.

The Lambert Initiative for Cannabinoid Therapeutics has been established at the University of Sydney following a donation of $33.7 million dollars. The Lambert Initiative is investigating the potential of compounds derived from the cannabis plant (cannabinoids) in treating a

[18] Medicinal Marijuana: NSW to run trials for epileptic children, terminally ill adults and cancer patients. 21 December 2014. Available at http://www.abc.net.au/news/2014-12-21/medicinal-marijuana-nsw-govt-to-run-trial-for-epileptic-children/5981648. Accessed 22 June 2016. $3 million was allocated in the 2016-17 NSW budget for the three medicinal cannabis trials for children with severe drug resistant epilepsy, people in palliative care and people with chemotherapy induced nausea and vomiting. Available at http://www.health.nsw.gov.au/news/Documents/20160621_02.pdf. Accessed 14 July 2016.

[19] Australian first medical cannabis trial begins in NSW. 27 July 2015. Available at: http://www.health.nsw.gov.au/news/Documents/20150727_00.pdf. Accessed 22 June 2016.

[20] Martin JH and Bonomo YA. Medicinal cannabis in Australia: the missing links. MJA 2016; 204 (10): 371-373.

[21] Medical cannabis trial for chemo patients. 26 February 2016. Available at http://www.health.nsw.gov.au/news/Documents/20160226_00.pdf. Accessed 22 June 2016.

[22] NSW Ministry of Health. Medicinal cannabis trials for children with severe epilepsy. Available at http://www.health.nsw.gov.au/cannabis/Documents/medicial-cannabis-practitioners.pdf. Accessed 22 June 2016.

range of diseases. Their approach will involve medicinal chemistry, cellular and preclinical research, early human testing and clinical trials in patients.[23]

One of the studies underway is the Paediatric Epilepsy Lambert Initiative Cannabinoid Analysis (PELICAN) study. The researchers are hoping to interview as many families as possible in order to learn about how medicinal cannabis is helping their children. The researchers will take samples of the oils from cannabis plants families are illegally sourcing and analyse them to see what cannabinoids they contain.

New South Wales compassionate access scheme for Epidiolex®

New South Wales has established a compassionate access scheme for Epidiolex®, a cannabidiol containing medicine that is being investigated for its effect in drug-resistant epilepsy in randomized clinical trials. Limited information is available about the efficacy and safety of using Epidiolex® to treat people with epilepsy, but the clinical studies underway have shown promising results.

The compassionate access scheme is part of the agreement between the New South Wales Government and GW Pharmaceuticals to explore the use of cannabinoid medicines for children with severe treatment-resistant epilepsy. The scheme provides access for children who are ineligible for other trials due to the severity of their condition.

[23] University of Sydney. News. 12 June 2015. Lambert donation puts Australia at forefront of medicinal cannabis research. Available at http://sydney.edu.au/news/84.html?newsstoryid=15109. Accessed 22 June 2016.

Appendix III: Availability of medicinal cannabis products

There are currently no legal medicinal cannabis products available or marketed for use in Australia. The only medicinal cannabis product that is approved by the TGA for use in Australia is the GW Pharmaceuticals product Sativex®. Sativex® contains nabiximols 80 mg/mL in a metered dose aerosol and is indicated for symptom improvement in patients with moderate to severe spasticity due to MS who have not responded adequately to other anti-spasticity medication, and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. While Sativex® is a registered medicine it is not currently marketed in Australia.

Products registered overseas include nabilone (Cesamet®), which is indicated for the treatment of chemotherapy induced nausea and vomiting that has not responded to conventional antiemetic treatment, and dronabinol (Marinol®) for the treatment of anorexia in patients with AIDS and chemotherapy induced nausea and vomiting that has not responded to conventional antiemetic treatment. Insys Therapeutics is undertaking trials in the USA of an oral liquid preparation of cannabidiol in the treatment of Dravet Syndrome and Lennox Gastaut Syndrome.

Some pharmaceutical grade plant material and plant extracts are being used overseas, but not as registered medicines, these include Bedrocan and Tilray products.

It is not clear at present whether states and territories other than New South Wales will be able to source experimental pharmaceutical products such as Epidiolex®[24] from GW Pharmaceuticals for use in individual patients, or what the cost might be if supply is feasible.

The establishment of the national licensing scheme for cultivation of cannabis for medicinal use and manufacture of products will enable a sustainable supply of medicinal cannabis products for Australian patients in the future. If in the immediate future a medical practitioner wishes to prescribe medicinal cannabis for a patient, it is likely an unregistered medicinal cannabis product would have to be imported from overseas. Sourcing these products may be difficult and expensive and as these products have been evaluated for efficacy or safety by the TGA.

It is anticipated that a small number of Australian manufactured products may become available in 2017. These products will also be unregistered medicines and will not have been evaluated for safety or efficacy by the TGA. Prescribers will similarly need to obtain approval from the TGA to access these medicinal cannabis products. Cannabis medicines that might be available will not be available as subsidised medicines under the Pharmaceutical Benefits Scheme.

[24] Epidiolex® is a Schedule 4 poison (Prescription Only Medicine).

Appendix IV: Patient access to medicinal cannabis in other jurisdictions

The Australian Capital Territory, New South Wales, Queensland, Tasmania, Victoria and Western Australia have announced patient access parameters for medicinal cannabis.

Australian Capital Territory

A medicinal cannabis scheme will be established in the ACT to give people safe and legal access to high quality medicinal cannabis products. The ACT Government is working to develop a considered and consistent framework to support a medicinal cannabis scheme as soon as practicable.

Evidence-based guidelines will be developed to inform and support medical practitioners in how to best prescribe medicinal cannabis products.

Two expert advisory committees will be appointed:

- a Medicinal Cannabis Medical Advisory Panel will provide high level advice to the Chief Health Officer on development of clinical guidelines and regulations;
- a Medicinal Cannabis Advisory Group will provide advice to government on the broader economic, legal and social issues related to the introduction of a medicinal cannabis scheme.

The ACT government expects the Medicinal Cannabis Scheme to be in place in 2017.

New South Wales

Under recent changes to NSW legislation, a medical practitioner who holds an authority granted by the Secretary, New South Wales Health may prescribe or supply a medicinal cannabis product for a person. The prescriber must also hold an approval issued under the Commonwealth Department of Health TGA Special Access Scheme, Authorised Prescriber scheme or Clinical Trial schemes.

The intention is that authorities are only granted to specialist medical practitioners to prescribe medicinal cannabis products only for patients who are seriously ill and have exhausted all standard treatment options. The product applied for must be legally produced and manufactured to appropriate quality standards with evidence supporting use of the particular product for the relevant patient.

The range of conditions that medicinal cannabis may be prescribed for is not limited to a specific range of indications. Applications for authorities will be reviewed by a committee of medical experts.

Queensland

The Queensland Government has passed legislation that makes the use of medicinal cannabis possible as a treatment for certain conditions. Medical conditions where cannabis products might be considered are muscular spasms and other symptoms of multiple sclerosis, chemotherapy-induced nausea and vomiting, some types of epilepsy with severe seizures, and some symptoms of HIV/AIDS-related symptoms. The Public Health (Medicinal Cannabis) Bill 2016 was introduced into the Queensland Parliament on 10 May 2016.[25]

When TGA rescheduling of medicinal cannabis occurs, regulations will be made such that:

[25] Queensland to pursue nation's most progressive medicinal cannabis regime. Available at http://statements.qld.gov.au/Statement/2016/2/29/queensland-to-pursue-nations-most-progressive-medicinal-cannabis-regime. Accessed 22 June 2016.

- Paediatric neurologists, oncologists and palliative care medical practitioners will be authorised to prescribe medicinal cannabis for patients in their care (Patient-Class Prescriber Pathway).
- There will also be a single-patient prescriber pathway (where a patient is ineligible to be treated under a Patient-Class Prescriber Pathway). A prescriber would apply to the Chief Executive of Queensland Health for approval to prescribe medicinal cannabis. Applications will be assessed on a case-by-case basis. An expert advisory panel will assist the Chief Executive in deciding whether to approve use in an individual patient. Approval is also required from the TGA for use and importation (where necessary) of the product.

The amount of medicinal cannabis that may be dispensed at any one time would be limited as a means of reducing the risk of diversion.[26]

Tasmania

The Tasmanian Government is developing a Controlled Access Scheme to allow patients to access unregistered medicinal cannabis products under prescription from their treating medical specialist in limited circumstances where conventional treatment has not been successful.[27]

Applications for approval to prescribe medicinal cannabis will be reviewed by a panel of specialist medical practitioners.
Patients will be required to sign a consent form acknowledging and accepting the risks associated with use of an unapproved medicine.[28]
The scheme will facilitate access to medicinal cannabis products grown lawfully under the Commonwealth licensing scheme, when they come onto the market.

Victoria

Victoria is establishing a medicinal cannabis access scheme that takes account of the recommendations in the Victorian Law Reform Commission Medicinal Cannabis Report August 2015 (the Report).[29]

The Report proposed access to medicinal cannabis in exceptional circumstances according to defined eligibility criteria and a licensing scheme for cultivation and manufacture of medicinal cannabis in Victoria.

The Report identified a set of conditions and symptoms as the basis for initially making medicinal cannabis available:

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[26] Public Health Medicinal Cannabis Bill 2016 Speech-Introduction of the Bill into the Queensland Parliament. 10 May 2016. Available at http://www.parliament.qld.gov.au/documents/tableOffice/BillMaterial/160510/Cannabis.pdf. Accessed 22 June 2016.
[27] Seriously ill Tasmanians to get access to medicinal cannabis from 2017. Available at http://www.abc.net.au/news/2016-04-23/doctors-to-prescribe-medicinal-cannabis-in-tasmania/7352844. Accessed 22 June 2016.
[28] Factsheet Medical Cannabis Controlled Access Scheme. Available at https://www.dhhs.tas.gov.au/__data/assets/pdf_file/0012/217110/Medical_Cannabis_Fact_Sheet.pdf. Accessed 22 June 2016.
[29] The Report is available at http://lawreform.vic.gov.au/projects/medicinal-cannabis/medicinal-cannabis-report-pdf.

- Severe muscle spasms or severe pain resulting from multiple sclerosis
- Severe pain resulting from cancer, HIV or AIDS
- Severe nausea, severe vomiting or severe wasting resulting from cancer, HIV or AIDS (or the treatment thereof)
- Severe seizures resulting from epileptic conditions where other treatment options have not proven effective or have generated side effects which are intolerable for the patient
- Severe chronic pain where, in the view of two specialist medical practitioners, medicinal cannabis may in all the circumstances provide pain management that is superior to what can be provided by other options.

The only eligible condition at present is severe seizures resulting from epileptic conditions where other treatment options have not proven effective or have generated side effects which are intolerable for the patient.

The use of medicinal cannabis products will only be permitted under medical supervision with supply via pharmacies. A specialist medical practitioner will need to make the decision that use of medicinal cannabis is appropriate.

The specialist medical practitioner must apply for a permit to issue an Authority to Dispense Medicinal Cannabis from the Secretary of the Victorian Department of Health and Human Services before authorising a patient to use medicinal cannabis. The permit is valid for 12 months.

The medicinal cannabis products supplied under the scheme will be assessed for quality but not for efficacy or safety.

An Independent Medical Advisory Committee has been convened. One of the Committee's first tasks is to determine which patients groups will next be eligible to access medicinal cannabis under the scheme.

It is anticipated:

- a small number of patients (children with severe epilepsy unresponsive to conventional treatments) will receive treatment under the Victorian scheme in 2017;
- a larger number of patients will receive treatment under the scheme in 2018.

Initially the Victorian Government will operate the entire scheme including cultivation of the cannabis and manufacture of the medicinal cannabis products.

The Victorian Government allocated $28.5 million in the 2016-17 budget for implementation of the scheme, including setting up an Office of Medicinal Cannabis that will be responsible for all clinical and manufacturing aspects of the scheme. Funding of $2.9 million was allocated in the 2016-17 budget for families that cannot afford medicinal cannabis.

Western Australia

From 1 November 2016 it is legal for a doctor to prescribe, and a pharmacist to dispense, medicinal cannabis in Western Australia with relevant approvals. A specialist doctor can prescribe a cannabis-based product subject to strict conditions, including obtaining permission from the TGA and the Western Australia Department of Health. Only some medical conditions will be suitable for approval to use medicinal cannabis products.

Appendix V: Requirements under the Controlled Substances (Poisons) Regulations 2011 relevant to prescriptions and orders for drugs of dependence for human use[30]

Giving a prescription for a drug of dependence by telephone or some form of electronic transmission other than fax

If a prescriber gives a prescription for a drug of dependence by telephone or some form of electronic transmission (other than fax) the prescriber must give the pharmacist the date of birth of the person for whom the prescription is intended (r33(3)(a)(viii); and

must, immediately after giving the prescription by that method, complete a written prescription that—

(i) clearly states it is given in confirmation of the prescription given by telephone or by electronic transmission (as the case may be) on the particular date when it was so given; and

(ii) otherwise complies with these regulations; and

must forward the written prescription to the pharmacist within 24 hours of giving the prescription by telephone or by electronic transmission (r33(3)(b) & (c)).

Giving a prescription for a drug of dependence by fax

If a prescription for a drug of dependence is given to a pharmacist by fax the prescriber must forward the original prescription to the pharmacist within 24 hours of giving the prescription by fax, unless the prescriber has endorsed the prescription given by fax with the name and address of a single pharmacy at which the prescription may be dispensed (r33(4)).

Medication chart prescriptions

Regulation 33 does not apply to a prescriber who gives a prescription for a drug if—

(a) the prescription is a medication chart prescription; and
(b) the provisions of the National Health (Pharmaceutical Benefits) Regulations 1960 (Cth) applying to the giving of a medication chart prescription for a pharmaceutical benefit are complied with in relation to the giving of the prescription for the drug (whether or not the drug is a pharmaceutical benefit) (r33(6)).

Writing a prescription for a drug of dependence

A prescription for a drug of dependence for human use must comply with the following additional requirements:

(i) the date of birth of the person for whom the prescription is intended must be included on the prescription;

(ii) the total amount of the drug to be supplied each time the prescription is dispensed must be expressed in both words and numerals;

(iii) a record must be kept of the details required to be included and specified on a written prescription under regulation 34.

[30] The requirements that are additional to those applying to prescriptions and orders for Schedule 4 poisons and the exemptions that apply to drugs of dependence. For complete information about the requirements refer to the Controlled Substances (Poisons) Regulations 2011.

Regulation 34 does not apply to a person who gives a prescription for a drug (including a drug of dependence) if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the National Health (Pharmaceutical Benefits) Regulations 1960 (Cth) applying to the giving of a medication chart prescription for a pharmaceutical benefit are complied with in relation to the giving of the prescription for the drug (whether or not the drug is a pharmaceutical benefit) (r34(4)).

Dispensing a drug of dependence on prescription

A pharmacist or medical practitioner who dispenses a drug of dependence on prescription must record the person's date of birth if the drug is dispensed for a person (r35(1)(b)(v)(A)).

A pharmacist must keep the record of supply of a drug of dependence on prescription in electronic form and transmit that record electronically to the Chief Executive[31] so that it is received no later than the seventh day of the month following the month in which the drug was dispensed (r35(1)(f)).

A pharmacist or medical practitioner who dispenses a drug of dependence on a prescription must—

(a) retain the original prescription or a copy of the prescription for a period of at least 2 years; and

(b) keep it readily available for inspection by an authorised officer; and

(c) on request by an authorised officer—send a copy of the prescription to the authorised officer (r35(1b)).

A pharmacist in charge of a pharmacy at which no drugs of dependence are dispensed for a period of 30 consecutive days must, no later than the 7th day of the month following the month during which the 30th day of that period falls, notify the Chief Executive of that fact in writing (r35(2)).

If, pursuant to subregulation (4)[32], a pharmacist or medical practitioner dispenses a drug of dependence at an earlier interval than that specified on the prescription, the pharmacist or medical practitioner must notify the prescriber of that fact in writing (r35(5)).

A pharmacist or medical practitioner must not dispense a drug of dependence if it is more than 6 months after the date on which the prescription was written (r35(7)(a)((i)(A)).

A pharmacist or medical practitioner must not, in respect of a drug of dependence—

(a) dispense more than 2 days' supply of the drug unless at least 1 of the following applies:

(i) the person for whose use the drug is prescribed is known to the pharmacist or practitioner;

[31] The Chief Executive, Department for Health and Ageing. In practice, prescriptions are transmitted to the Department's Drugs of Dependence Unit.

[32] If a pharmacist or medical practitioner is satisfied that a person—

(a) has lost a previously dispensed supply of a drug; or

(b) will, through absence from the State or otherwise find it unduly difficult to have future supplies of a drug dispensed as needed,

may (but is not obliged to) dispense a prescription at an interval earlier than that specified on the prescription (r35(4)).

(ii) the pharmacist or practitioner recognises the signature on the prescription as that of the prescriber who purportedly gave the prescription;

(iii) the pharmacist or practitioner has verified with the prescriber who purportedly gave the prescription that the prescription was in fact given by that prescriber (r35(8)(a)).

The dispensed drug of dependence must not be handed over to the person for whose use the drug is dispensed or his or her agent, until the person or his or her agent has signed and dated the prescription or a computer generated copy or faxed copy of the prescription; and unless the person or his or her agent is known to the pharmacist or medical practitioner, has produced satisfactory evidence of his or her identity (r35(8)(b)).

Regulation 35 (other than subregulations (1)(b), (1b) and (7)(a) and (b)) does not apply to a pharmacist or medical practitioner who dispenses a drug on a prescription if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the National Health (Pharmaceutical Benefits) Regulations 1960 (Cth) applying to the sale or supply of a pharmaceutical benefit have been complied with in relation to the sale or supply of the drug (whether or not the drug is a pharmaceutical benefit) (r35(12)).

Special restrictions on prescription or supply of drugs of dependence by registered health practitioners and veterinary surgeons

A person must not prescribe or supply a drug of dependence for use by his or her spouse, domestic partner, parent, grandparent, child, grandchild, brother or sister unless—

(a) the prescription or supply is authorised by the Minister; or

(b) the prescription or supply is in circumstances of a verifiable emergency (r37(1)).

This subregulation does not apply to the supply of a drug of dependence by a pharmacist if the pharmacist is dispensing a prescription for the drug (r37(3)).

A registered health practitioner must not prescribe or supply a drug of dependence for use by himself or herself unless the prescription or supply is in circumstances of a verifiable emergency (r37(2)).

Records to be kept by manufacturers of drugs of dependence

Regulation 39 specifies the records that must be kept by manufacturers of drugs of dependence.

A manufacturer of a medicinal cannabis product would have to hold a licence and permit for manufacture granted under the *Narcotic Drugs Act 1967* (Cth). The manufacturer would also have to comply with any conditions on the licence and permit granted under the Australian Government licensing scheme in relation to record-keeping.

Records to be kept by sellers and suppliers of drugs of dependence

There are requirements relating to the records that must be kept by a supplier of a drug of dependence (e.g. a pharmacist) when he or she sells or supplies a drug of dependence. Information must be recorded about the supplier, the person to whom the drug is sold or

supplied, the date of sale or supply, the drug and the quantity of drug sold or supplied and the invoice number (if any) for the sale or supply of the drug (r40(1)(a)).

The record of sale or supply must be made in electronic form and the supplier must transmit the record electronically to the Chief Executive so that it is received no later than the 7th day of the month following the month in which the drug was sold or supplied (r40(1)(c)). This requirement does not apply to—

(a) persons licensed under the Act to manufacture drugs of dependence or sell drugs of dependence by wholesale; or
(b) pharmacies (including health service pharmacies) in respect of the supply of drugs of dependence to a health service facility (r40(2)).

The supplier must make a record of the amount of the drug now in stock on the premises from which the drug was sold or supplied and sign the record (r40(1)(a)(ii)).

The record of sale or supply must be kept at all times on the premises from which the drug of dependence was supplied (r40(3)).

A supplier must not supply a drug of dependence in accordance with an order—

(a) unless the supplier has reasonable cause to believe the person who ordered the drug is lawfully authorised to do so; and
(b) unless the person receiving the drug—
    (i) provides the supplier with a signed and dated receipt for the drug; and
    (ii) is known to the supplier or produces satisfactory evidence of his or her identity (r 40(4)).

A supplier who sells or supplies a drug of dependence on an order must—

(a) retain the original order or a copy of the order for a period of at least 2 years; and
(b) keep it readily available for inspection by an authorised officers; and
(c) on request by an authorised officer—send a copy of the order to the authorised officer (r40(1a)).

The Minister may exempt a supplier or class of suppliers, from regulation 40, or specified provisions of regulation 40, if satisfied that the supplier, or class of suppliers, has adequate arrangements for the keeping of records.

Records to be kept by suppliers of drugs of dependence who receive such drugs

If a supplier of drugs of dependence receives such a drug, or a person receives a drug of dependence from a supplier on order, the person receiving the drug must record information about the person who provided the drug, the person who took delivery of the drug, the date on which the drug was received, the drug, the amount of the drug, and if the drug was provided on order, the invoice number (if any) for the supply of the drug. The supplier must make a record of the amount of the drug in stock on the premises at which the drug was received and sign the record (r41(1)).

The person receiving the drug must give to the person who provided the drug a signed and dated receipt for the drug (r41(1)(a)).

The record must be kept at all times on the premises at which the drug was received (r41(2)).

The Minister may exempt a person, or class of persons, from regulation 41, or specified provisions of regulation 41, if satisfied that the person, or class of persons, has adequate arrangements for the keeping of records and the security of drugs of dependence (r41(3)).

Supply or administration of drugs of dependence by registered health practitioners

Regulation 42(1) specifies the details a registered health practitioner (who is not a pharmacist) must keep when he or she administers a drug of dependence to a person or supplies a drug of dependence for use by a person. Information must be recorded about the registered health practitioner, the person to whom the drug is administered or supplied, the drug, including the amount supplied or administered, the date and time at which the drug was supplied or administered and the amount of drug (if any) remaining in stock on the premises at which the drug is supplied or administered. The registered health practitioner must sign the record.

If an error in the record is discovered, the person authorised to make the record must correct it in the specified way (r42(3)).

The Minister may exempt a registered health practitioner, or class of registered health practitioners, from regulation 42 or specified provisions of regulation 42, if satisfied that the registered health practitioner, or class of registered health practitioners, has adequate arrangements for the keeping of records (r42(4)).

Additional requirements for the administration of drugs of dependence in a health service facility

Regulation 44 specifies additional requirements for the administration of drugs of dependence in a health service facility. There are requirements for:

- documenting the prescribed instructions for the administration of a drug of dependence to a person in a health service facility;
- the drug must be administered to the person by a registered health practitioner in accordance with all instructions in the person's medication record;
- the administration of the drug of dependence must be witnessed by a registered health practitioner, or, if a registered health practitioner is not reasonably available by some other responsible person. The name and signature of the person who witnessed the administration of the drug must be recorded;
- how prescribed instructions for the administration of a drug of dependence are given by telephone and how the instructions are documented in the person's medication record. The practitioner who gave the instructions by telephone must, within 48 hours of giving the instructions by that method, endorse the relevant entries in the medication record with his or her signature and the date (r41(1));
- stock counts of the drugs of dependence in the ward at the end of the shift and for reporting any discrepancy in the count (r44(2)(b));
- a nurse or midwife must be designated as having responsibility for the record-keeping requirements for the ward for a particular shift (r44(3)).

The manager of the health service facility must take all reasonable steps to ensure that—

(a) all drugs of dependence delivered to the health service facility or a ward of the health service facility are received by a registered health practitioner

employed by the health service facility or, if such a practitioner is not reasonably available, by some other responsible person; and

(b) an accurate and up-to-date balance of stocks of all drugs of dependence in each ward of the health service facility is maintained at all times; and

(c) the requirements of regulation 44 are complied with (r44(5)).

The Minister may exempt a health service facility, or class of health service facilities, from regulation 44 or specified provisions of regulation 44, if satisfied that the health service facility, or class of health service facilities, has adequate arrangements for the administration of drugs of dependence (r44(5a)).

Destruction of drugs of dependence

A person must not destroy a drug of dependence unless the destruction is witnessed by another person, being—

(i) an authorised officer; or

(ii) a police officer; or

(iii) a registered health practitioner; or

(iv) a veterinary surgeon; or

(v) a person who has been authorised in writing by the Chief Executive of the SA Ambulance Service to administer drugs of dependence (r45(1)(a)).

The person destroying the drug of dependence must ensure the specified information about the destruction is recorded (r45(1)(b)).

Regulation 45 does not apply to the destruction of a drug of dependence by—

(a) a person for whose use the drug was lawfully prescribed or supplied; or

(b) a police officer or an authorised officer (r45(2)).

Retention of records, drugs of dependence register

Records made under the regulations relating to drugs of dependence must be retained for a period of two years from the day on which the entry was made. During that time all reasonable steps must be taken to ensure the records are protected against deterioration, loss, theft and unauthorised access, modification or use.

The records must be readily available for inspection at all reasonable times (r49(1)).

The details required to be recorded under the regulations in respect of drugs of dependence must, unless otherwise specified, be recorded in a drugs of dependence register. If the details are recorded in an electronic drugs of dependence register, the form of the electronic register must be approved by the Minister (r49(3)).

A receipt required to be provided to a person under the regulations must be kept by that person in the manner set out in this regulation as if it were a record (r49(4)).