CANNABIS-BASED PRODUCTS FOR MEDICINAL USE
Title: Cannabis-based Products for Medicinal Use

1. Background

The Commonwealth Government has amended the Narcotic Drugs Act 1967 to create a licence and permit scheme, allowing the cultivation of cannabis and manufacture of cannabis-based products for medicinal and research purposes.¹

Under these amendments, a licence or permit to manufacture medicinal cannabis must be for a product that is:

- for medical research that can be approved by the Therapeutic Goods Administration (TGA);
- on the Australian Register of Therapeutic Goods (ARTG); or
- otherwise authorised or approveable under the Special Access Scheme or Approved Prescriber Scheme.

From 1 November 2016 cannabis-based products for medicinal are classified as Schedule 8 substances (Controlled Drugs) by the national Poisons Standard² when produced or manufactured in accordance with the Narcotic Drugs Act³.

Changing attitudes to medicinal use of cannabis in Australia is creating demand for access to cannabis-based products, for conditions that are claimed by patients to be inadequately managed by conventional therapies.

There are large scale, and preliminary research studies, already underway or commencing, in a number of medical settings, both overseas and within Australia. However, the evidence base for medicinal cannabis is still limited in quality, and there is a pressing need for high-quality research into the potential roles and safety profiles of cannabis-based products in treating a range of medical problems.

Current political and social pressures at times combine, to conflate the need for scientific research, with requests for compassionate access by individual patients. Most patient demand is currently presented as requests for compassionate access to cannabis-based products.

The supply of therapeutic goods throughout Australia is controlled by Commonwealth Law, including the Therapeutic Goods Act 1989 administered by the Therapeutic Goods Administration.⁴ Therapeutic Goods Legislation establishes and maintains a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used or produced in Australia.

Prescription medicines are specialised and high-risk therapeutic goods that are captured and regulated by Therapeutic Goods Legislation. This provides consumer protection and confidence that products; contain exactly what they say they do each and every time, do not contain unknown or harmful ingredients, work the way they say they will, are well made through the use of good manufacturing practices, and will not cause undue harm.

There are arguments made that in certain exceptional circumstances, cannabis-based products might be made accessible outside a research setting, on a compassionate basis, in advance of the normal evidence and quality standards that apply to other medicines.
2. Purpose

The Cannabis-based Products for Medicinal Use Policy (the Policy) provides regulatory, research and governance guidance to health services and health practitioners in relation to medicinal cannabis.

The Policy is part of the Public Health Policy Framework.

3. Applicability

In Western Australian, drugs and poisons Legislation applies to all Scheduled medicines. This policy applies to any health practitioner or other staff member employed in the WA health system required to obtain, possess, store, prescribe, administer, dispense or supply a cannabis-based product for medicinal purposes as a Scheduled medicine.

Requirements for adherence to ethical, scientific and site-specific assessment of research, as well as principles of research under the Research Policy Framework apply to all Health Service Providers (HSPs).

Compliance, monitoring and the evaluation of compliance, with the requirements for Scheduled Medicines, Controlled Drugs and Therapeutic Goods under Western Australian and Commonwealth Legislation are both the personal and shared responsibility of:

- Authorised Health Professionals;
- License and Permit Holders;
- Health Service Providers; and
- Any individual conducting medical research within a HSP.

Under Legislation, compliance breaches may result in serious criminal penalties, including: for persons; court prosecution, custodial sentences, fines and penalties, and for health practitioners; conditions, restrictions or revocations of professional authorisation.

4. Policy Statement

4.1 Regulatory Policy

The Poisons Standard is a national classification system, adopted by all States and Territories of Australia. Any Schedule 8 item lawfully prescribed and dispensed within Australia may be legally possessed and used by a patient in Western Australia.

Western Australia adopts the Schedules of the Poisons Standard by reference; any medicine in Schedule 8, including cannabis-based products, is captured by Western Australian Poisons Legislation.

Schedule 8 substances are Controlled Drugs which are those that; “should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.”

The classification of cannabis-based products as a Controlled Drug recognises that they have potential legitimate therapeutic uses, and like other medicines in this class also have potentially serious side effects and can cause dependence in some people. As Controlled Drugs, cannabis-based products will be treated like morphine, ketamine, alprazolam, dexamphetamine and other medicines in Schedule 8, already in regular medical use.
The Poisons Act 1964\(^5\) and Poisons Regulations 1965\(^6\) are the established Poisons Legislation that control the supply of medicines and poisons in Western Australia.

The Poisons Legislation regulates the purchase, possession, use, prescribing and supply of Scheduled medicines, including Controlled Drugs. This Legislation provides a legal framework for access to medicines by patients, through qualified health practitioners, while ensuring adequate public protection.

This Legislation is an effective and appropriate mechanism for the supply and use of cannabis-based products. Regulations that apply to any Controlled Drug in Western Australia, equally apply to cannabis-based products, regardless of setting, and whether for treatment with registered therapeutic products, research purposes, or compassionate access.

**Prescription medicines require medical supervision for safe consumer use.**

Prescription medicines are intended for the treatment of significant and serious illness. They are potentially toxic poisons that can cause severe harm if improperly used. The decision to prescribe a cannabis-based product must be made by a qualified medical practitioner. Controlled Drugs are prescription only medicines; the supply of any cannabis-based product requires the valid authority of a medical practitioner.

**Prescription medicines require supply by pharmacists, acting in their profession as trained and regulated health practitioners.**

Controlled Drugs may only be dispensed by a pharmacist. Pharmacists are registered health practitioners, skilled in handling medicines, and have specific expertise in the supply and management of Controlled Drugs.

**Poisons Legislation prevents the diversion of Controlled Drugs into settings where they may be abused or misused.**

The Poisons Legislation establishes and protects the integrity of the medicines supply chain. Health practitioners handling Controlled Drugs are accountable to ensure security, safe storage, tracking and record keeping of these substances, including for cannabis-based products.

The Poisons Legislation complements the Narcotic Drugs Act to ensure the seamless, regulated movement of cannabis-based products, from Commonwealth licenced and permitted cultivators and manufacturers, through to State licensed pharmaceutical wholesalers and authorised health practitioners, including pharmacies, and then to patients.

**Legislation regulates the prescribing of cannabis–based products, as Controlled Drugs, so as to protect the health of both the individual and of the public.**

Poisons Legislation governs medical practitioners when prescribing Controlled Drugs, based on medical criteria such as: specialist prescriber group; medical condition; type of patient; or medicine or product.

These are established regulatory controls designed for prescribing of Controlled Drugs, which also apply to the prescribing of Schedule 8 cannabis-based products. Prescribing under these regulations should be evidence based and consistent with the most contemporary medical research on efficacy and safety.

A consistent national approach to prescribing is required, where patient access to cannabis-based products in Western Australia, as in other States and Territories, is guided by the consensus of recognised medical experts and regulatory authorities. Regulation
The Western Australian Government does not support the recreational use of cannabis.

Medicinal cannabis is lawful when the cultivation, manufacture, prescribing and supply is in compliance with all applicable Commonwealth and State or Territory laws. The use of cannabis, sourced in any other way is not legal, even if for purported medicinal reasons. Changes to Commonwealth and State laws for medicinal cannabis-based products do not legalise the recreational use of cannabis.

Cannabis for non-medicinal use remains in Schedule 9 of the Poisons Standard and cannot be lawfully prescribed or supplied under Western Australian Poisons Legislation. Schedule 9 substances are prohibited by law and penalties for possession and trafficking apply under the *Misuse of Drugs Act 1981*.

Figure 1: Medicines supply chain for cannabis-based products: regulatory environment

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**SCHEDULE 8 CANNABIS PRODUCTS** – Medicinal use (legal)

- **State Laws**
  - Poisons Act
  - Narcotic Drugs Act
  - Therapeutic Goods Act

- **Commonwealth Laws**
  - Poisons Act
  - Therapeutic Goods Act

**SCHEDULE 9 CANNABIS** – Recreational use (Illegal)

- **Misuse of Drugs Act (State - Police)**
4.2 Research Policy

WA health system research principles are documented in the Research Policy Framework.

Research endorsed by the WA health system has the purpose of improving health outcomes and health system performance, while contributing to wider social and economic benefits for the community.

The Research Policy Framework clearly outlines the philosophies of the WA health system supporting and managing research. Key objectives of the Research Policy Framework are to:

- ensure research effort across the WA health system will be conducted in accordance with the highest ethical and scientific standards;
- comply with relevant Legislation, policies, standards, codes of conduct and national best practice guidelines; and
- support the consistent management of Research Governance and Intellectual Property across the WA health system.

Complying with the Research Policy Framework helps to ensure that any WA health system supported research is likely to answer the questions being asked in a scientifically robust and ethically sound manner.

Studies of medicinal uses of cannabis-based products require scientific integrity, including clearly specified entry and exit criteria, well defined and measurable outcomes, and adequate study numbers. Ideally, interventional research will be undertaken in randomised, controlled studies, in order to improve the validity of the findings, and transferability across different treatment settings.

In some circumstances open-label studies may be appropriate in order to answer questions that cannot otherwise be assessed. Open-label studies are those that do not use a comparative or placebo control and where the treatment supplied is known to the treating practitioner and patient.

The cannabis-based products studied shall be well analysed, consistent, stable and of adequate purity to ensure that unwanted pharmacological effects from a range of metabolites do not occur, and be deliverable in a form that provides predictable dosing, without unwanted side-effects of the delivery system.

Research that will enhance our understanding of medicinal uses of cannabis-based products, measurable patient benefits, and potential treatment applicability in specific conditions, will be deemed as suitable and only when in keeping with the Research Policy Framework.

The purpose of medicinal cannabis research will be to improve therapeutic outcomes for patients, contribute to the knowledge base around the specific conditions and patients who may benefit from these products, improve understanding of pharmacology, and potentially contribute to the development of new drug products.

Research governance will be managed in accordance with the Western Australian Health Research Governance Policy and Procedures 0411/2012 directive.

This includes ensuring that any research studies will undergo review and approval by the relevant Human Research Ethics Committee and complies with research governance processes so that research is conducted in accordance with the organisation’s...
Many requests will be for compassionate access to cannabis based products for a limited range of conditions including; multiple sclerosis, chemotherapy induced nausea and vomiting, intractable epilepsy and palliative care.

The outcomes of compassionate access use practices should be recorded and monitored; however, this process is to be considered a form of clinical audit, rather than research. This type of access is not part of the Research Policy Framework and cannot be funded under normal mechanisms for funding research projects.

Figure 2: Research process and principles for cannabis-based products

- Develop research question
- Construct research proposal
- Establish investigation team
- Obtain funding and compile budgets
- Obtain human research ethics approvals
- Obtain governance authorisations
- Scientific, feasibility and ethical assessments
- Meet site specific and organisational requirements
- Register and list trial
- TGA, NHMRC
- Source cannabis-based intervention product
- Undertake study
- Prescribe and supply product under close medical supervision
- Monitor progress
- Patient safety, reporting requirements, protocol adherence
- Conduct analysis of results
- Project Closure
- Final reports, records management
- Publish and disseminate findings

ADHERENCE TO PRINCIPLES FOR SCIENTIFICALLY ROBUST AND ETHICAL MEDICAL RESEARCH

ADHERENCE TO STATE AND COMMONWEALTH LAWS
4.3 Compassionate Access Policy
The negative health effects of recreational and illicit cannabis use are well categorised in the medical literature. Less is known about the long-term safety of cannabis-based products in patients, when used for medicinal purposes and under medical supervision.

The longer term health effects of medicinal use of cannabis-based products are still largely unknown and further research is necessary. The study of prescription medicines in clinical research settings is part of the scientific process to establish the basis for safety and efficacy of a treatment or product.

Research studies are designed to be limited to the time needed to answer the specific medical questions they pose. The results of this research inform wider therapeutic use and where a treatment or product is shown to be safe and effective, products are expected to then enter the normal processes for registration and regulation of therapeutic goods.

Medicinal cannabis products should meet the normal expectations of Australian consumers that the prescription medicines they take are safe, effective and of good quality.

To be lawfully supplied in Australia, prescription medicines must comply with Commonwealth Therapeutic Goods Legislation and have been assessed as meeting recognised standards by the national medicines regulator. Ultimately, all cannabis-based products should be held to the existing standards for medicines.

Only medicines registered on the Australian Register of Therapeutic Goods are assured as being assessed by the national regulator and determined to meet these standards.

Therapies and products in use within a research setting, by definition are being studied for the purpose of obtaining information on efficacy and safety. Therapeutic Goods laws make provision to legally conduct clinical research on unregistered products. These studies should meet requirements of Therapeutic Goods Legislation relating to conduct of clinical trials and products tested should meet all associated quality standards for research, as necessary.

While research continues to accumulate, cannabis-based products lawfully manufactured under the Narcotic Drugs Act, or lawfully imported from overseas schemes and intended for medicinal use within Australia, may not yet be registered therapeutic goods.

Therapeutic Goods Legislation makes provision for the authorisation or approval of unregistered products. This affords potentially lawful avenues of access to these products, which patients or prescribers may seek to exercise. Any use of a product that is not a registered therapeutic good, and is not used within an approved research setting, is considered to be compassionate access in nature.

In these cases, the prescribing of a cannabis-based product might be in advance of accepted medical evidence and outside recognised medical opinion. Such products will not have been assessed by regulators against Australian standards for medicines and therefore definitive statements about quality may not be possible.

Prescribing and supply of compassionate access products may place increased obligations on prescribers and dispensers in relation to; medical justification and ethics of treatment, steps taken to ascertain or assure quality of a given product, patient understanding of risks and informed consent, liability and other matters.
Prescribers are strongly cautioned regarding entry into compassionate access use of cannabis-based products, to ensure they adhere to professional standards, serve only the best medical interests of the patient, and exercise all due care.

**Public funding of medicines does not support the supply of unregistered and unapproved products.**

HSPs through larger public hospitals, maintain mechanisms for compassionate access to unregistered medicines. Where maintained these programs may approve access to medications that are not listed on the HSP Medicines Formulary, are not listed on the Pharmaceutical Benefits Scheme, or have not undergone assessment by the Therapeutic Goods Administration.

Applications for compassionate access are made by a clinician, for use of a specified product, in an individual patient, for a particular condition. Typically, approval is given for a specified period of time, and extension is dependent upon ongoing evidence of benefit in the individual patient.

Any compassionate access to cannabis-based product shall be:

- Formerly requested by the treating Clinician; and
- Assessed and approved according to all existing HSP governance and quality processes for medicines.

Access programs are heavily limited to those circumstances judged as exceptional according to strict criteria. Routinely, requests involve the scrutiny and agreement of the Health Service Drugs and Therapeutics Committee.

**Access to cannabis-based products for compassionate reasons shall comply with all State and Commonwealth laws.**

There are a number of regulatory schemes in Australia for medicines, that work together to keep the public safe from substandard or harmful products, misleading claims, unscrupulous practices, and illicit diversion and misuse.

The prescribing of any cannabis-based product must comply with Western Australian Legislation; whether for registered products, research settings, or compassionate access purposes. Any cannabis-based product sourced and manufactured in Australia must comply with Commonwealth Narcotic Drugs Legislation; whether for registered products, research settings, or compassionate access purposes.

Prescribers, suppliers and dispensers shall obtain all relevant Commonwealth authorities and approvals for any compassionate use. This may include any necessary permission under *Therapeutic Goods Legislation*, and compliance with any stated conditions. The import of any cannabis-based product into Australia as a Controlled Drug, even if lawfully prescribed to a patient, must comply with relevant Commonwealth Legislation on importation of narcotic drugs, prohibited or restricted items, and therapeutic goods.
Figure 3: Compassionate access: safety, efficacy and quality

5. References

1. Narcotic Drugs Amendment Act 2016
2. Poisons Standard March 2016
3. Scheduling delegate’s final decisions: Cannabis and Tetrahydrocannabinols, March 2016
4. Therapeutic Goods Administration
5. Poisons Act 1964
6. Poisons Regulations 1965
8. WA Health Research Governance Policy and Procedures - OD 0411/12

6. Relevant Legislation

- Narcotic Drugs Amendment Act 2016
- Poisons Act 1964
- Poisons Regulations 1965
7. Policy custodian

Chief Pharmacist
Office of the Chief Health Officer

Enquiries relating to this policy may be directed to:
PoisonsInfoLine.PHD@health.wa.gov.au

8. Review

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9. Authority

This policy has been approved and issued by the Director General of the Department of Health as the System Manager.

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