

# The medicinal use of cannabis, today

# Contributed by Martin Woodbridge

In March, 2025, the Medical Council of New Zealand convened an interagency hui to assess the regulatory, safety and educational needs for the medicinal use of cannabis in New Zealand. The discussions exposed critical challenges to the legitimate, safe and effective use of this new class of medicines. Similar concerns have emerged in Australia, underscoring a need for co-ordinated regional strategies. In light of this noteworthy development, Martin Woodbridge, pharmacologist and regulatory policy analyst, provides an update to our audience, alongside pragmatic solutions to current challenges.

# A brief history of medicinal cannabis in New Zealand

Cannabis has medicinal value. It can be used as a medicine. It is not a medicine by default.

New Zealand has established a legacy of good regulatory policy. In 2010, *Sativex*®, an oromucosal spray containing THC and CBD, classified as a Class B1 Controlled Drug, became the first approved medicinal cannabis product¹ following the development of regulatory policy and clinical guidance. The Misuse of Drugs (Medicinal Cannabis) Regulations 2019 brought into effect domestic production, minimum quality standards,² and simplified prescribing and dispensing of unapproved medicinal cannabis products in 2020.³ The supply of medicinal cannabis products has since increased markedly. The developments in New Zealand represent a common thread in the global context. A scientific review by the World Health Organization resulted in the UN Commission on Narcotic Drugs formally recognising the medical value of cannabis in 2020.⁴

# The pharmacological basis of cannabis as a medicine

The pharmacological basis of the action of cannabis is well-established. The body's endocannabinoid system is a lipid-based cell-signalling network that modulates physiological homeostasis – regulating neurotransmission, immune activity and metabolic processes. Endocannabinoids are lipid-based retrograde neurotransmitters that exhibit biological activities like those of plant-derived cannabinoids. The pharmacological effects of cannabinoids are mediated through specific cannabinoid receptors. Two types of cannabinoid receptors—CB1 and CB2—have been identified; both belong to the G-protein-coupled receptor superfamily. 5, 6

The cannabis plant (*Cannabis sativa* L.) produces pharmacologically active cannabinoids, principally delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). These phyto-cannabinoids are substrates for the cytochrome P450 enzyme family—particularly CYP3A4, CYP2C9 and CYP2C19—which also means that there is potential for clinically significant medicine interactions, especially in a polypharmacy context.

## Therapeutic use of cannabis and clinical evidence

Medicinal cannabis is not a panacea. It is prescribed in general practice, and in pain, oncology and palliative care settings, to manage the symptoms of various chronic conditions, often as an adjunct treatment in patients who may not have responded adequately to other medicines.

The clinical evidence base is incomplete but is improving steadily. The most consistent and high-quality data support the use of THC and THC:CBD formulations in addressing the affective dimensions of pain, improving appetite and sleep quality, and treating moderate to severe spasticity in patients with multiple sclerosis. High-dose CBD has demonstrated efficacy in reducing seizure frequency in treatment-resistant epilepsies, particularly in paediatric populations. For other proposed indications, the evidence remains low quality or inconclusive.

While medicinal cannabis generally exhibits a favourable safety profile, transient physiological, psychological and neurological adverse effects, such as dizziness, anxiety and cognitive impairment, are common with higher doses of products containing THC. Treatment discontinuation is frequently linked to excessive dosing of either THC or CBD, which can amplify adverse effects and compromise tolerability.

For further information, see Fleisch, Woodbridge & Burgess, 2025, sections: Current Situation, Pharmacology and Prescribing.

# Translating clinical research to clinical practice

Although clinical trials involving standardised medicinal cannabis products have significantly advanced our understanding of their safety and therapeutic potential, translating these findings into routine clinical practice remains a persistent challenge.

The commercial landscape is currently characterised by substantial variability in dosage formats, formulations and product specifications. This heterogeneity undermines consistency in prescribing and compromises patient outcomes. The lack of product standardisation also limits the feasibility of robust post-market surveillance, impeding our efforts to monitor safety and real-world effectiveness.

As a result, pharmacovigilance systems for cannabis-based treatments remain fragmented or non-functioning. Evaluation outside of controlled trials is inconsistent, further obstructing the development of evidence-informed prescribing protocols.



# The status in our region

As of October, 2025, approximately 61 medicinal cannabis products have been verified as meeting New Zealand's minimum quality standard under the Medicinal Cannabis Scheme.<sup>2</sup> While these products may be delivering clinical benefit, persistent challenges continue to undermine the integrity of the Medicinal Cannabis Scheme. N.B. A verified product (i.e. meeting the minimum quality standard) is not the same as an approved medicine; non-verified medicinal cannabis products are also still able to be accessed in New Zealand.

Key concerns here are mirrored in Australia. These include the proliferation of dosage forms and administration devices, non-standard medicine nomenclature (some with very inappropriate names), manufacturing quality changes between production batches and inconsistent availability of products at the agreed quality standard. It is also important to note that a paucity of clinical data for most products continues to hamper evidence-informed decision-making. Other potential issues include safety concerns with high-potency THC products, particularly in vulnerable patient groups such as young people, frail elderly people and people with mental illness. There are also concerns some prescriber communities have biases on prescribing specific products, have an incentive or are pressured, to prescribe, and may prescribe outside the current clinical evidence base.

Indeed, in New Zealand, while the emergence of specialised cannabis clinics has expanded patient access, it has also raised concerns about the privatisation of prescribing, the erosion of integrated care and patient co-management, and financial conflicts of interests blurring clinical judgement.8 Researchers Rychert and Wilkins note that the programme has resulted in a rapid increase in the supply of medicinal cannabis products, reduced prices and an expanded range of products, in particular THC-dominant products. From 1 May, 2023, to 30 April, 2024, a total of 164,979 product units of medicinal cannabis were prescribed in New Zealand:9,10

- 55.6% were CBD or balanced THC:CBD products
- 45.4% were THC products (75,121 units), specifically:
  - 17.7% THC-dominant flower administered by vaporisation (29,318 units)
  - 21.6% THC-dominant flower administered as tea (35,757 units)
  - 6.1% THC-dominant oral solutions or sprays (10,046 units)

www.bpac.org.nz 2 November 2025

Prescribing high-dose THC products to males aged 18 – 45 years poses a potential public health risk, given the elevated prevalence of cannabis use disorder in this demographic. This group is already recognised as having a heightened susceptibility to substance dependence, raising concerns about long-term safety and treatment appropriateness.<sup>11, 12</sup>

Certain dosage forms, such as cannabis 'teas', are particularly problematic. These formulations exhibit poor and variable bioavailability, are often derived from lower-grade dried flower, and may be administered via inhalation, compounding potential harm. Their inconsistent pharmacokinetics undermine therapeutic predictability and complicate clinical monitoring.

Pharmacists face persistent operational challenges in managing cannabis flower products.<sup>13</sup> These include high-volume Class C1 Controlled Drug storage requirements, compounded by non-standard medicine naming conventions and variable dosage formats. Such variability impairs effective batch tracking and compromises the integrity of pharmacovigilance systems.

In New Zealand, the Section 29 pathway provides a legal mechanism for accessing unapproved medicinal cannabis products on a named-patient basis. However, the widespread use of large volumes of unapproved products across a broad patient population raises safety concerns, as these products have not undergone Medsafe's full assessment for safety, efficacy and quality. Section 29 of the Medicines Act 1981 is intended for case-by-case, practitioner-led access—not for general distribution. In this context, adherence to the minimum quality standard, labelling and advertising requirements is paramount to safeguard patient safety and clinical integrity.

# Safe and rational use - what can primary care do?

Primary care has a pivotal role in initial patient assessment for suitability of medicinal cannabis products, ongoing management and co-management with other specialists where appropriate. Therefore, a sound understanding of medicinal cannabis as a treatment option is increasingly important in both care settings.

# Assessing patient suitability: Initial evaluation and prescribing considerations

Patients may hold strong views on medicinal cannabis—some will arrive well-informed, while others may be unfamiliar with its therapeutic use. Prescribers must be equipped to engage in meaningful conversation to assess whether unapproved medicinal cannabis or an approved cannabis medicine is appropriate for the condition and the patient.

If medicinal cannabis is deemed suitable, clinicians must discuss risks, benefits and uncertainties openly with patients, obtain informed consent and set expectations around treatment goals, duration and review.

For further information, see: The RNZCGP position statement on medicinal cannabis prescribing, and the patient suitability flow chart proposed by Fleisch, Woodbridge & Burgess, 2025.

#### **Managing uncertainty**

Prescribing and dispensing medicinal cannabis is multifaceted. The clinical trial evidence base is incomplete, particularly for first-line use. Variability in product cannabinoid content, dosage form and bioavailability adds further complexity. Almost all products are unapproved and are often controlled drugs containing THC. Many require administration devices (e.g. vaporisers, syringes, sprays, droppers) and have tailored dosing schedules.

Medicinal cannabis is generally well tolerated, with dose-dependent adverse effects. However, medicine interactions may occur, and some patients have contraindications to treatment (e.g. cardiovascular conditions, pregnancy, psychosis). Adverse effects with high doses of CBD can result in worsened symptom control, sleepiness, abnormal liver function and diarrhoea. High doses of THC may result in physiological, psychological and neurological symptoms such as tachycardia, anxiety, psychomotor impairment or sedation.

Prescribing unapproved medicines or prescribing medicines off-label carries an inherent risk.<sup>14</sup> Medical practitioners must obtain informed consent, discuss available evidence and safety considerations and assume full responsibility for prescribing decisions. Pharmacists, in addition to fulfilling documentation and dispensing requirements, should counsel patients on the unapproved status of the medicine and associated risks.

The involvement of a specialist in pain medicine, oncology or palliative care is essential for managing complex cases; they can evaluate the suitability of cannabis-based treatment in the context of concurrent medicines and the broader management plans. Patients need to clearly understand the onset time and duration of effect, and potential adverse effects (e.g. anxiety, sedation, impaired cognition) associated with different doses and dosage forms of medicinal cannabis. Advise patients of absolute contraindications and precautions when using THC-containing products.

## Prescribing considerations – safety, efficacy and risk mitigation

Medicinal cannabis is often a second or third-line treatment and used as an adjunct. Many patients will be co-prescribed other medicines, therefore consider the potential for interactions and how they will be identified and managed.

## Exercise caution when co-prescribing medicines:

- That interact with CYP450 enzymes (e.g. CYP3A4, CYP2C9, CYP2C19)
- With sedative effects, as THC may impair response time, co-ordination and concentration. N.B. Use with alcohol should also be avoided.
- That affect cardiovascular function, as THC can cause a transient rise in blood pressure and heart rate

#### Familiarise yourself with dosage forms, dosing protocols, and titration schedules:<sup>15</sup>

- Preferentially select standardised formulations, such as oromucosal sprays, formulated oral solutions or vaporisation capsules, over irregular preparations like loose-leaf teas, which exhibit poor bioavailability and unpredictable pharmacokinetics
- Prioritise products with a lower-THC content (< 20% w/w or v/v), unless higher concentrations are clinically justified and supported by titration protocols and monitoring plans
- Remain vigilant for product-associated side effects, potential adverse reactions and device-related risks (e.g. vaporiser malfunction, mucosal irritation, dosing errors)

#### Pay particular attention to the following patient groups:

- Patients with cardiovascular risk factors, hepatic or renal impairment or a history of psychosis or depression—these conditions may amplify susceptibility to adverse effects, particularly with THC-containing products
- Frail and elderly patients, who are more vulnerable to side effects such as orthostatic hypotension, sedation and cognitive impairment
- Paediatric patients (aged < 18 years)—avoid prescribing unless clinically justified and under specialist supervision, given developmental neurotoxicity concerns and limited safety data
- Young adult males (aged 18 45 years)—especially those requesting high-THC products or reporting prior substance use.
   Monitor closely for signs of misuse, diversion, dose escalation or emerging dependence.

## **Choice of administration**

Consider what dosage form would be most practical and effective for the patient. The dosage form directly affects bioavailability and therefore the actual dose delivered. While there is no evidence that a pulmonary dose is better than an oromucosal dose, the former offers the advantage of a more rapid onset of action and shorter active period.

Table 1. Administration method considerations. Adapted from Fleisch, Woodbridge & Burgess, 2025.15

	Pulmonary (vapour inhalation)	Oromucosal (sublingual & buccal)
Onset of clinical effects	5 – 10 minutes	30 – 90 minutes
Duration	1 – 3 hours	6 – 8 hours
Positives	Rapid onset of action, advantageous for acute or episodic symptoms, easy to titrate to an optimal dosage  Vaporiser medical devices minimise harms from inhalation	Fast absorption and onset of action, long duration of action Various dose forms – droppers, sprays, wafers
Negatives	Upfront expense and knowledge of the device	Part of the dose may be swallowed, absorbed and metabolised  A high level of dexterity is required for some devices (e.g. droppers)

4 November 2025 www.bpac.org.nz

# Preparing a treatment plan: Dosing, titration, monitoring and cessation



As with any medicine, medicinal cannabis should be prescribed at the lowest possible dose that achieves the desired clinical effect with minimal adverse effects. A conservative dosing protocol is recommended if there are any concerns about tolerance, adverse effects or medicine interactions.

## **Key considerations:**

- Pharmacological effects are dose-dependent and subject to interpatient variability
- Systemic absorption varies in timing and intensity depending on the route of administration

Table 2 provides approximate pharmacokinetic properties for THC-containing products, by route of administration. The medicine data sheet or New Zealand Formulary (for an approved product) or product information should be consulted for product-specific prescribing information.

**Table 2.** Pharmacokinetics of THC, by route of administration.

Route	Dose	Cmax	Onset	Duration	
Inhalation vapour	Up to 20 mg	80 ng/mL16	5 – 10 minutes	1 – 3 hours	
Oromucosal spray	5 – 15 mg	THC: 2 – 4 ng/mL17	30 – 90 minutes	6 Ohours	
		11-OH-THC: 1.8 – 5.2 ng/mL	90 – 180 minutes	6 – 8 hours	

N.B. Oromucosal administration results in the partial hepatic metabolism of THC and moderate 11-OH-THC formation. The half-life of THC is 24 - 36 hours and is 12 - 24 hours for 11-OH-THC. Vaporisation devices may yield  $\leq 50\%$  of available cannabinoids depending on device, temperature and inhalation technique.<sup>18, 19</sup>

#### **Dose titration**

Provide clear guidance to the patient on the starting dose and titration process, including how dosage adjustments will be made.

A titration period is essential to establish a personalised therapeutic dosage. Depending on the indication, start with evenly spaced doses throughout the day, adjusted according to individual response and tolerability. Gradually increase the dose until the optimal daily dose is reached—defined as the greatest therapeutic benefit with minimal side effects.

#### Principles for titration:

- **Start low, go slow:** dosing time and frequency depend upon the indication. Initiate with multiple small doses, rather than a single large dose, to cumulatively reach the target dose for a therapeutic effect. Maintain a low total daily dose during the initial phase.
- Allow time for response: maintain the same low dose and total daily dosage for several days and monitor clinical response before adjusting
- Incremental increases: cautiously increase the dose, as required, allowing time between adjustments to assess
  efficacy and tolerability
- **Optimal daily dose:** slow, incremental increases allow patients to reach an optimal daily dose. The treatment protocol can then be monitored.

#### Monitoring

Schedule clinical reviews frequently during the early phase of treatment to assess tolerability, therapeutic response and adherence. Identify and respond to red flags such as rapid dose escalation beyond expected titration curves, repeated early refill requests or signs of misuse or diversion.

Collaborate with pharmacists to reinforce patient understanding of dosing protocols and administration techniques and device operation. Pharmacists should ensure consistency between prescribing instructions and dispensing labels, and address patient uncertainty at the point of supply.

Advise patients to pause upward titration immediately if adverse effects emerge, and to report this promptly to their clinician or pharmacist. Report all adverse medicine events and device malfunctions to <u>CARM</u> and <u>Medsafe</u>, respectively. This supports continuous improvement of product quality and clinical guidance.

#### Cessation

The treatment plan should include agreed treatment goals and how therapeutic effect will be measured. Establish a clear plan to discontinue or modify treatment if it proves ineffective, causes intolerable side effects or if misuse or dependence is identified. Confirm a protocol for the return of unwanted or unused medicines, and, where applicable, the administration device.

# **Pragmatic solutions to current challenges**

The future of the medicinal use of cannabis depends on addressing key clinical and regulatory challenges. There is a pathway forward. The following are actionable steps to address these issues.

**Promoting the rational use of medicinal cannabis is paramount** <sup>20</sup>—these are mainly unapproved products with limited or no clinical data associated with them.

**Education is necessary.** It is key to rational medicine use. The uptake of clinical education contributes to reducing variability in prescribing, dispensing and administration. The Clinical Primer on Cannabis text offers a robust foundation for safe and effective prescribing, dispensing and administration. It is a RNZCGP-endorsed resource and is freely available at: clinical primer cannabis.com. The bpac<sup>nz</sup> article on the medicinal cannabis scheme framework provides a useful précis for health professionals to understand the programme. A separate guide for pharmacists is also available.

A comprehensive appraisal of available formulations, dosage formats and associated devices is needed, regularly updated to reflect emerging clinical evidence, and made available via a central reference point. This will allow New Zealand prescribers and pharmacists to familiarise themselves with suitable dosage forms, dosing protocols and titration schedules.

**Timely and consistent enforcement of medicinal cannabis regulations** is essential to reduce ambiguity and mitigate current risks. Priority areas include dosage form standardisation, medicine nomenclature, product labelling and the regulation of therapeutic claims. Greater uniformity across these domains will enhance the capacity of post-market surveillance systems to monitor prescribing practices, product quality and patient safety. Such regulatory coherence is critical to sustaining the integrity and long-term effectiveness of the Medicinal Cannabis Scheme.

## About the author

**Martin Woodbridge** is a pharmacologist and regulatory policy analyst with a focus on the rational use of medicines and medicine quality standards. He trained and lectured at the Wellington School of Medicine, University of Otago, and held roles at Medsafe and the Ministry of Health, where he led New Zealand's medical cannabis regulatory policy and clinical quidance development in 2007.

He has advised both government and non-government organisations, including the United Nations International Narcotics Control Board (INCB). His technical and policy contributions have supported regulatory development in Southeast Asia and the Pacific. In the United States, he is a member of ASTM International and collaborates with the United States Pharmacopeia to advance cannabis medicine quality standards.

Martin is the author of A primer to medicinal cannabis and co-author of A clinical primer – a guide to the rational use of cannabis-based medicines.

6 November 2025 www.bpac.org.nz

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