The Royal New Zealand College of General Practitioners
Te Whare Tohu Rata o Aotearoa

POSITION STATEMENT

Medicinal cannabis prescribing

Summary of position

Specialist GPs are sometimes faced with the need to help patients who are unable to manage chronic and debilitating conditions using conventional, evidence-based treatments, and, at times, patient requests to prescribe medicinal cannabis products. However, as with all clinical decisions, GPs need to balance patient-initiated requests for treatment and the clinician's therapeutic responsibility. It is also imperative to consider legislative and professional requirements before prescribing medicinal cannabis products.

The Royal New Zealand College of General Practitioners (the College):

- neither recommends nor encourages the use of medicinal cannabis products; however, it recognises that as specialists, GPs may offer to prescribe medicinal cannabis products. The sole medicolegal responsibility for prescribing rests with the prescriber.
- has assessed the evidence about the safety and effectiveness of medicinal cannabis products that have not been approved as medicines by Medsafe and has found it to be limited and inconclusive.
- asserts that medicinal cannabis products should only be considered when all first-line, conventional, evidence-based treatment options have been exhausted.
- supports specialist GPs who, based on their clinical assessment, decline to prescribe or to issue a repeat prescription in response to patient requests for medicinal cannabis products that have not been approved as medicines by Medsafe.
- reminds specialist GPs that if they have concerns about the prescribing or recordkeeping of a prescriber, they should talk to them directly in the first instance. If their concerns remain, they should consider notifying the Medical Council of New Zealand or the Health and Disability Commissioner.

Summary of recommendations

In summary, the College recommends that:

- high-quality research into the safety and effectiveness of medicinal cannabis products be conducted.
- balanced, evidence-based education for the general public and medical practitioners be made available.
- the Government start monitoring the prescribing and use of medicinal cannabis products to increase confidence in the Medicinal Cannabis Scheme.
- the Government ensures that prescribers of medicinal cannabis products cannot also supply or dispense medicinal cannabis products to patients.

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Context

The regulatory regime[i] for medicinal cannabis in New Zealand changed in 2020 to make it easier for specialist GPs and other registered medical practitioners to prescribe cannabis medicines and products.

The Ministry of Health and bpac[nz] have produced a College-endorsed quick reference card as a guide to prescribing medicinal cannabis (included as Appendix 1). It provides an overview of the Medicinal Cannabis Scheme, a schematic of the regulatory decisions a prescriber needs to make, and a basic prescribing checklist.[1] A fuller description of the law around medicinal cannabis and when and how it should be prescribed is set out in the bpac[nz] web-based resource An overview of medicinal cannabis for health practitioners.[2]

Sativex® oral spray and Epidyolex® oral solution are currently the only cannabis-based products in New Zealand that has been approved as medicines by Medsafe under the Medicines Act 1981.[ii] Sativex® is indicated for the treatment of spasticity due to multiple sclerosis. Epidyolex® is indicated as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) for patients two years of age and older. Any other uses of Sativex® and Epidyolex® are unapproved uses of these medicines. At this time, no other cannabis products have been assessed as safe and effective medicines by Medsafe.[3]

'Therapeutic' cannabis products that have been approved by the Medicinal Cannabis Agency as meeting minimum quality product standards are listed on its website.[3] None of these products have been assessed for safety and efficacy by Medsafe. None of these products are approved medicines in New Zealand.

Medicinal cannabis products that have not been approved by Medsafe or the Medicinal Cannabis Agency can be prescribed by registered medical practitioners. These products, however, have no official New Zealand endorsement of efficacy, safety or quality, and there are more restrictive access requirements, particularly if the product meets the definition of being a controlled drug.[2]

The prescribing of cannabidiol (CBD) medicinal cannabis products that contain little-to-no tetrahydrocannabinol (THC) and other related psychoactive substances are controlled under the Medicines Act 1981. Other medicinal cannabis products are controlled under the Misuse of Drugs Act 1975.[4]

The College has received reports that some prescribers are supplying and dispensing medicinal cannabis products to patients. When making prescribing decisions, this creates a potential conflict between the patient's and the prescriber's commercial interests.

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i The Medicinal Cannabis Scheme came into effect on 1 April 2020 with the commencement of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019. See https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicinal-cannabis-agency/about-medicinal-cannabis-scheme [cited 2023 Feb 14]

ii In the future, medicines will be controlled under Therapeutic Products Act 2023 (TPA). It is likely to be several years before the new Act takes effect. The TPA does not alter current settings in relation to medicinal cannabis and substances controlled under Misuse of Drugs Act 1975, and doctors and patients will still be able to access these products through the market authorisation pathway or the special-case pathway (clause 66 of the TPA).

No medicinal cannabis medicines or products are currently funded by Pharmac. Any application to fund medicinal cannabis would need to meet requirements of the Guidelines for Funding Applications to PHARMAC[5]. Key criteria include a defined patient population and symptoms, good quality supporting evidence, an appropriate comparator treatment and long-term outcome and safety data. Pharmac advises that it is unlikely to fund medicinal cannabis products that are not Medsafe approved. The application to fund Sativex®, a Medsafe-approved cannabis medicine, has not been approved, as Pharmac considers that the clinical evidence does not show that Sativex® is more effective than other medicines funded for the same uses.[6]

Pharmac does consider funding treatments for individuals under its Named Patient Pharmaceutical Assessment (NPPA) process if the person has tried all currently funded alternative treatments, has exceptional clinical circumstances and Pharmac has already considered the treatment for funding. Pharmac has considered over 80 NPPA applications for medicinal cannabis products. At January 2023, only eight had been approved and these were for individual patients with life-threatening and/or extremely severe conditions for which all other treatment options had been exhausted.[7]

Prescribing cannabis-based products

Specialist GPs are sometimes faced with the need to help patients who are unable to manage chronic and debilitating conditions using conventional, evidence-based treatments, and patient requests to prescribe medicinal cannabis products. However, before prescribing medicinal cannabis products, as with all clinical decisions, GPs need to balance patient-initiated requests for treatment and the clinician's therapeutic responsibility, while also considering legislative and professional requirements. For more information, refer to the Code of Health and Disability Services Consumers' Rights,[8] Medical Council of New Zealand (MCNZ) standards[9] and to Appendix 1 for bpac^{nz}'s quick reference card to prescribing medicinal cannabis. Relevant MCNZ standards include Good Medical Practice,[10] Good Prescribing Practice,[11] Informed Consent,[12] and Managing Patient Records.[13] Specialist GPs should also strive to provide continuous, comprehensive care that is built on diagnosis to identify health care needs in patients, their whānau and communities, to ensure timely and equitable care.[14]

This position statement neither recommends nor encourages the use of medicinal cannabis products; however, it recognises that as specialists, GPs may offer to prescribe medicinal cannabis products to patients with specific conditions in consultation with them and their care team. The sole medicolegal responsibility for prescribing rests with the prescriber.[15]

Importantly, our advice is that medicinal cannabis products should only be considered when all first-line, conventional, evidence-based treatment options have been exhausted, and after detailed discussions of the potential benefits and harms of medicinal cannabis products with the patient.[iii]

iii See for example Medical Council of New Zealand |Te Kaunihera Rata o Aotearoa. Good Prescribing Practice. March 2020: https://www.mcnz.org.nz/assets/standards/ceae513c85/Statement-on-good-prescribing-practice.pdf

It is appropriate for specialist GPs who are not knowledgeable or familiar with medicinal cannabis products that have not been approved as medicines by Medsafe to decline to prescribe or to issue a repeat prescription in response to patient requests. In the case of repeat medicinal cannabis prescriptions, the College reminds specialist GPs that if they have concerns about the prescribing or recordkeeping of a prescriber, they should talk to them directly in the first instance. If their concerns remain, they should consider notifying the Medical Council of New Zealand or the Health and Disability Commissioner.[16]

This position statement is consistent with those of the Royal Australian College of General Practitioners, the Nederlands Huisartsen Genootschap and the College of Family Physicians of Canada, which do not recommend prescribing cannabis products as a first-line treatment because of the lack of high-quality evidence of effectiveness and safety.[17–19]

Evidence base for medicinal cannabis

Currently, the evidence base for the use of medicinal cannabis products is limited. Based on advice from the Faculty of Pain Management (FPM) of the Australian and New Zealand College of Anaesthetists & Faculty of Pain Management, the Clinical Advisory Pharmacists Association (CAPA) and the College's review of the evidence,[20–30] the current evidence base is heterogeneous, comprising a small number of randomised clinical trials when categorised by condition, symptom or intervention type. These studies are of variable quality, including those with high risk of bias (e.g. incomplete outcome data), low statistical power, and short follow-up time.

While there is evidence of some therapeutic benefits of medicinal cannabis products for conditions such as multiple sclerosis, palliative care, epilepsy, nausea and vomiting, and chronic non-cancer pain, further research on the treatment efficacy and longer-term side effects is needed.[17] Indications and dosages need to be determined to help specialist GPs prescribe medicinal cannabis products with confidence.[2]

Equity

The College's kaupapa includes a commitment to equitable care and addressing health inequities.[31] The high cost of medicinal cannabis medicines and products makes them an unaffordable treatment option for many. The College has heard that this may drive some patients to obtain 'street' cannabis. Not only is this illegal, but such behaviours compromise patient safety and health.

These issues could be addressed if medicinal cannabis products were funded. However, as noted above, Pharmac does not currently fund any medicinal cannabis medicines or products and is unlikely to do so until products have been approved as medicines by Medsafe. Hence the College's call for further high-quality research into the safety and effectiveness of medicinal cannabis products. This will be necessary to support applications to Medsafe for cannabis products to become approved medicines.[32]

Recommendations

The College recognises that while there are significant community and political interests in the medicinal use of cannabis products for therapy, the evidence base for the safety and effectiveness of medicinal cannabis products is currently incomplete. The College therefore highlights the need for further high-quality research into the safety and effectiveness of medicinal cannabis products.

There is also a need to ensure that education for the general public and medical practitioners is available. This education should reflect the current state of knowledge and contextualise the use of medical cannabis products as a medication for specific categories of illness that should only be prescribed in rare circumstances after stringent legislative and professional requirements are satisfied. It should be developed and presented by appropriately qualified, independent, and well-known authorities, provide a balanced coverage of issues and contain no professional or commercial bias. Any sponsorship should be clear and have no bearing on the content or delivery.[33]

While preparing this position statement, the College became aware that the usage of medicinal cannabis products in New Zealand is not being monitored. The College therefore calls on the Government to put systems in place and to start monitoring the prescribing and use of medicinal cannabis products. The system should be designed to help monitor the effectiveness of the 2020 Medicinal Cannabis Scheme, as well as acute and long-term safety issues. The College would also recommend that the system includes the independent review of a sample of medicinal cannabis prescribing against legislative and professional standards to increase confidence in the Medicinal Cannabis Scheme.

The College calls on the Government to ensure that prescribers of medicinal cannabis products cannot also supply or dispense medicinal cannabis products to patients.

What next?

The College has always been a strong advocate for evidence-based medicine, and as the evidence around the efficacy and effectiveness of medicinal cannabis products evolves, this position statement will be reviewed.

This position statement will also be reviewed when it becomes clear how medicinal cannabis products will be regulated under the Therapeutic Products Act 2023. The commencement date for the new Act is currently unclear but must be before 1 September 2026.[34]

APPENDIX 1: A guide to prescribing medicinal cannabis quick reference card

Quick reference card:
A guide to prescribing medicinal cannabis

The **Medicinal Cannabis Scheme** (The Scheme) became operational on 1 April, 2020. The Scheme is administered by the **Medicinal Cannabis Agency** (part of the Ministry of Health), and aims to minimise barriers to prescribing medicinal cannabis, and improve patient access to quality products.

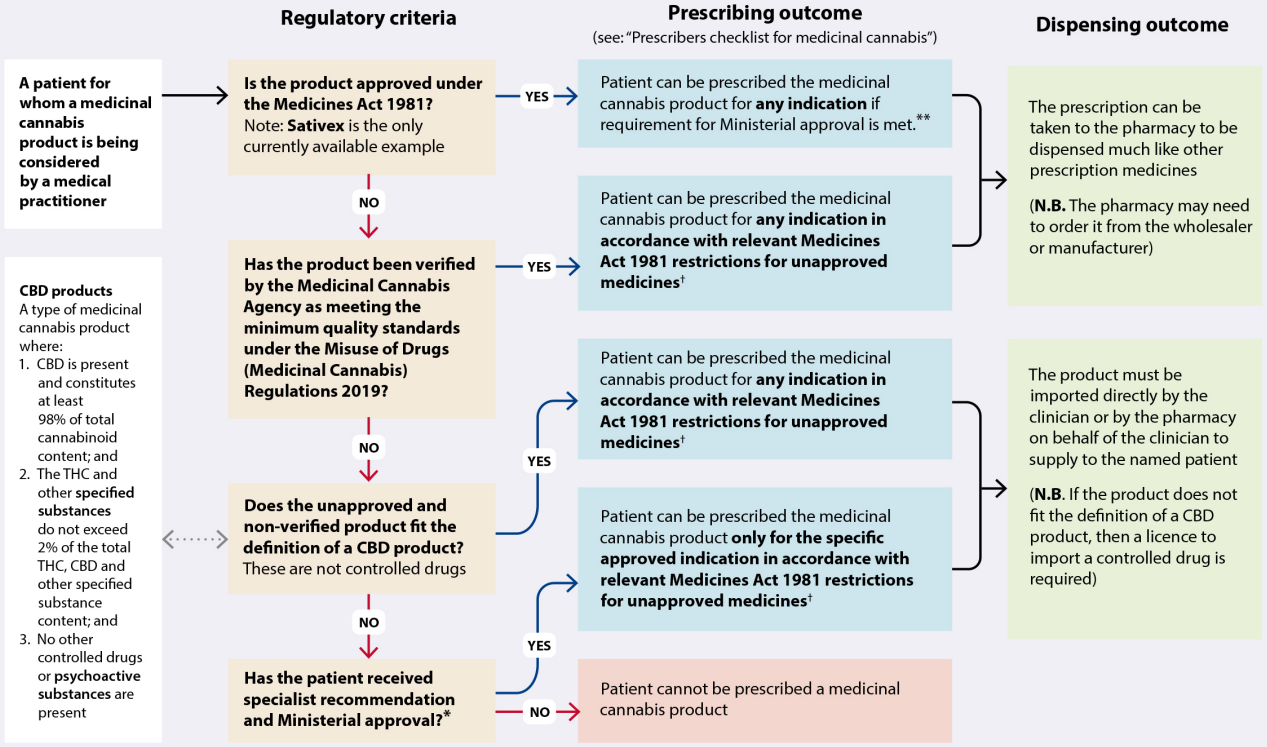
Under The Scheme, medicinal cannabis products that do not have Medsafe approval can be prescribed to patients if they are verified as meeting the **minimum quality standard** by the Medicinal Cannabis Agency. For a list of these products, see the Ministry of Health website.

The minimum quality standard is not an endorsement of safety or efficacy; it recognises that a product meets strict good manufacturing practice requirements, which ensures the consistency and quality of products. Unless a product obtains Medsafe approval, e.g. Sativex, it is an unapproved medicine, placing prescribers as the 'gate-keepers' to access for patients.

"Is medicinal cannabis suitable for my patient?"

See the main resource for more information, e.g. limited evidence by indication, safety considerations

How the new regulatory framework affects the prescribing of medicinal cannabis products by registered medical practitioners (i.e. doctors) in New Zealand



* An application form for Ministerial approval to prescribe non-pharmaceutical grade medicinal cannabis without consent for distribution is available on the Ministry of Health website. The application must be completed by a specialist who is managing the condition that the product is intended to treat or by the Chief Medical Officer of a District Health Board.

† Unapproved medicines must be prescribed by a medical practitioner and directly supplied to the patient by the prescribing medical practitioner, or dispensed by a pharmacy via Section 29 of the Medicines Act.

** All registered medical practitioners (i.e. doctors) have been granted Ministerial approval to prescribe Sativex without the need to submit an application to the Ministry of Health.

Prescriptions for medicinal cannabis products must:

- ☐ Be handwritten on a controlled drug prescription form (except for CBD products as they are not classified as controlled drugs), or on a personally signed barcoded controlled drug ePrescription
- ☐ Specify the brand and prohibit any generic substitutions; in some cases, prescribing software may automatically enable generic substitutions by default, so particular care should be taken to disable or remove this option if available
- ☐ Not be for a product in a form intended for smoking
- ☐ Not be for a product meeting the definition of "food" under the Food Act 2014
- ☐ Not be for a product in a sterile dosage form, e.g. eye drops
- ☐ Be prescribed for supply under Section 29 of the Medicines Act 1981 if the product is not Medsafe approved, after gaining and recording patient consent
- ☐ Be for no more than a one-month supply if a controlled drug (including Sativex)
- ☐ Be for no more than a three-month supply if a CBD product

Always establish a treatment plan with the patient, including:

- Treatment objectives
- Proposed timeframe
- Dosing strategy
- Risk management plan
- Monitoring criteria
- Discontinuation strategy

How to import a medicinal cannabis product for a named patient that lacks Medsafe approval and is not verified as meeting the minimum quality standards

- **CBD products:** no additional licences are needed, however, a certificate of analysis is required from the manufacturer which should accompany the import to confirm it is a CBD product
- **For non-CBD products:** in addition to Ministerial approval, a licence to import controlled drugs is required for each consignment, issued by Medicines Control (for further info, email Medicines control)

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