

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.

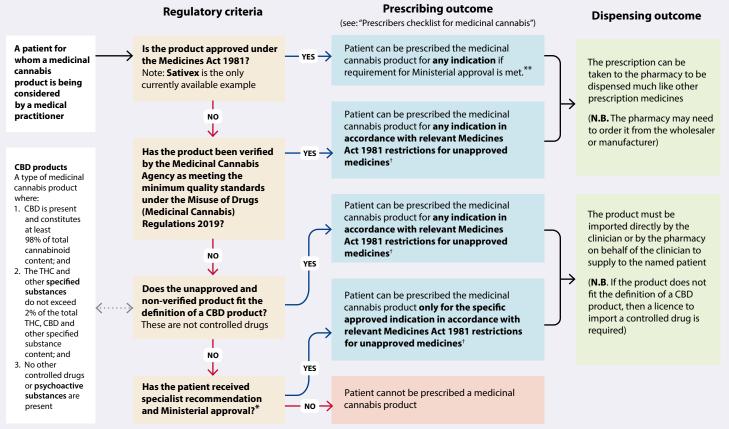
The minimum quality standard is not an endorsement of safety or efficacy; it recognises that a product meets strict good manufacturing practice requirements, which ensures the consistency and quality of products. Unless a product obtains Medsafe approval, e.g. Sativex, it is an unapproved medicine, placing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



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)