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.

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.

### 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

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

<table>
<thead>
<tr>
<th>Regulatory criteria</th>
<th>Prescribing outcome</th>
<th>Dispensing outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>A patient for whom a medicinal cannabis product is being considered by a medical practitioner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBD products: A type of medicinal cannabis product where: 1. CBD is present and constitutes at least 98% of total cannabinoid content; and 2. The THC and other specified substances do not exceed 2% of the total THC, CBD and other specified substance content; and 3. No other controlled drugs or psychoactive substances are present</td>
<td>Is the product approved under the Medicines Act 1981? Note: Sativex is the only currently available example</td>
<td>YES →</td>
</tr>
<tr>
<td>NO</td>
<td>Patient can be prescribed the medicinal cannabis product for any indication if requirement for Ministerial approval is met. **</td>
<td></td>
</tr>
<tr>
<td>Has the product been verified by the Medicinal Cannabis Agency as meeting the minimum quality standards under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>NO</td>
<td>Patient can be prescribed the medicinal cannabis product for any indication in accordance with relevant Medicines Act 1981 restrictions for unapproved medicines †</td>
<td></td>
</tr>
<tr>
<td>Does the unapproved and non-verified product fit the definition of a CBD product? These are not controlled drugs</td>
<td>YES</td>
<td>The prescription can be taken to the pharmacy to be dispensed much like other prescription medicines (N.B. The pharmacy may need to order it from the wholesaler or manufacturer)</td>
</tr>
<tr>
<td>NO</td>
<td>Patient can be prescribed the medicinal cannabis product for any indication in accordance with relevant Medicines Act 1981 restrictions for unapproved medicines †</td>
<td></td>
</tr>
<tr>
<td>Has the patient received specialist recommendation and Ministerial approval? *</td>
<td>YES</td>
<td>The product must be imported directly by the clinician or by the pharmacy on behalf of the clinician to supply to the named patient (N.B. If the product does not fit the definition of a CBD product, then a licence to import a controlled drug is required)</td>
</tr>
<tr>
<td>NO</td>
<td>Patient cannot be prescribed a medicinal cannabis product</td>
<td></td>
</tr>
</tbody>
</table>

* 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.

### 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)

### Always establish a treatment plan with the patient, including:

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

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