

# Medicinal Cannabis

## Regulatory Requirements for Prescribers

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# Overview of presentation

- Role of Medsafe
- Definitions
- Current prescribing requirements
- Recent legislative change
- Medicinal Cannabis Scheme

# Medsafe, Ministry of Health

- Medicines Act - substances used for a therapeutic purpose
- Psychoactive Substances Act
- Misuse of Drugs Act – controlled drugs
- Natural health products and foods – no controlled drugs or prescription medicines
- Exception hemp SEED foods

# Key definitions

- **Consented** means Medsafe approved for distribution in NZ based on an assessment of quality, safety and efficacy data provided by the sponsor of the product
- **Medicinal cannabis** is usually defined to mean all forms of products derived from the cannabis plant, including CBD products, that are used for medicinal purposes.

# CBD Product

## 2A Meaning of CBD product

(1) *CBD product* means a product that—

**(a)** contains [cannabidiol](#); and

**(b)** either—

**(i)** does not contain a specified substance; or

**(ii)** contains specified substances in an amount that is no more than 2% of the sum of the amount of [cannabidiol](#) and the amount of specified substances in the product; and

**(c)** does not contain any other controlled drug; and

**(d)** does not contain any other psychoactive substance (as defined in [section 9](#) of the Psychoactive Substances Act 2013).

# Specified substances

(2) In this section, *specified substance* means a substance that—

**(a)** naturally occurs in cannabis; and

**(b)** is—

**(i)** a tetrahydrocannabinol; or

**(ii)** an isomer, ester, or ether of a tetrahydrocannabinol; or

**(iii)** an ester or ether of an isomer of a tetrahydrocannabinol; or

**(iv)** a salt of any substance described in subparagraphs (i) to (iii); or

**(v)** a substance that has a structure substantially similar to that of any substance described in subparagraphs (i) to (iv); and

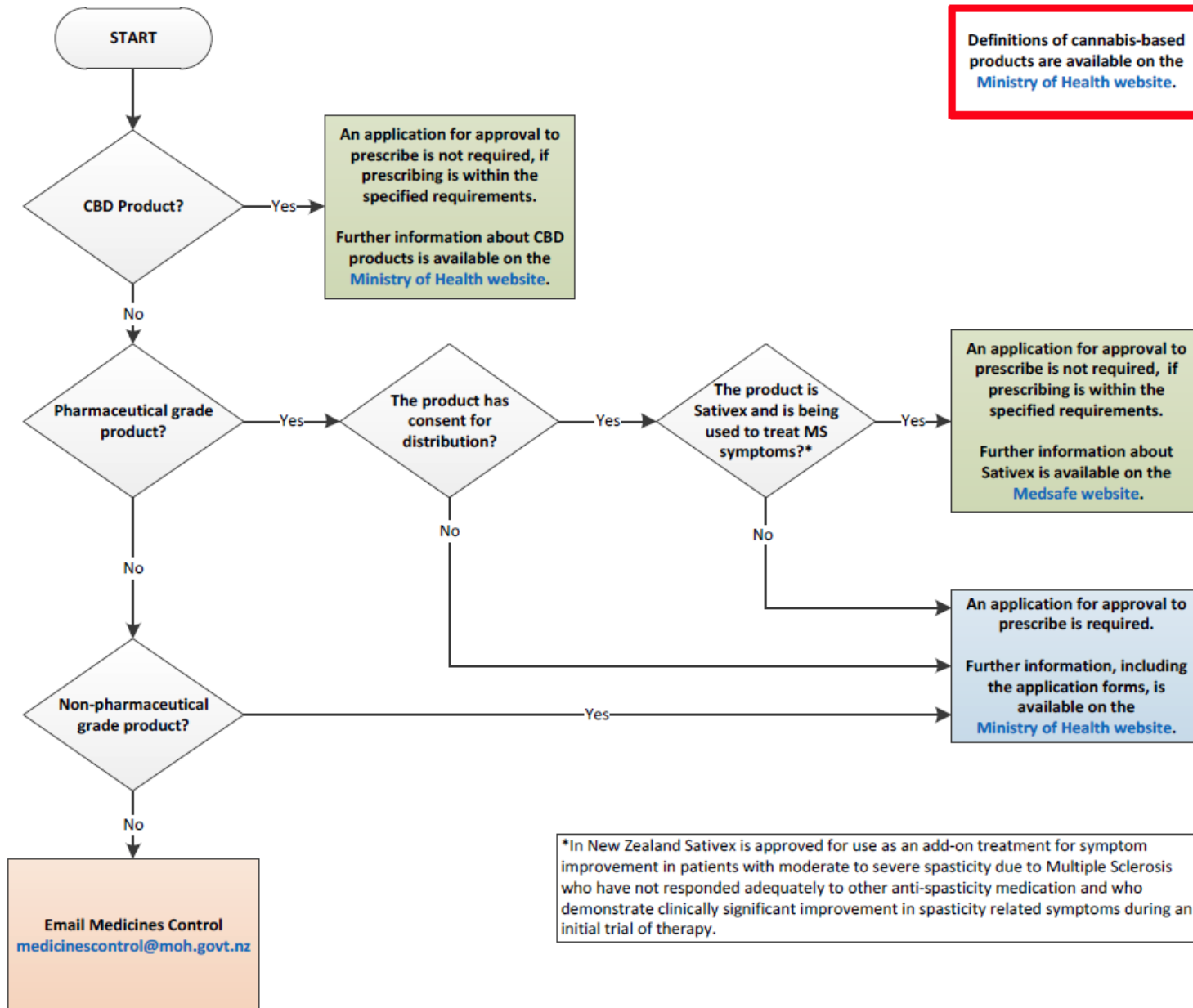
**(c)** for substances listed in paragraph (b)(ii) to (v), is capable of inducing more than a minor psychoactive effect, by any means, in a person.

# Current requirements for prescribing medicinal cannabis

- Forms and detail at <https://www.health.govt.nz> Search for “prescribing medicinal cannabis products”
- Prescribing requirements have been gradually modified to reduce barriers to access
- Ministerial approval to prescribe

# Approvals to Prescribe Medicinal Cannabis

Definitions of cannabis-based products are available on the [Ministry of Health website](#).





# Prescribing non-consented products

- Apart from Sativex, all products including the CBD products are non-consented
- Cannot be advertised
- Can only be prescribed by medical practitioners
- Informed consent must be obtained

# Legislative changes

## Misuse of Drugs (Medicinal Cannabis) Amendment Act 2018

- CBD no longer a controlled drug; still a prescription medicine
- People requiring palliation have statutory defence for use of cannabis or possession of a cannabis utensil
- Allows regulations to be made to prescribe standards for cultivation, manufacture, and for medicinal cannabis products
- Allows a licence holder to use locally sourced cannabis plants, fruit and seeds
- Requires regulations to be made by 18 December 2019

# Medicinal Cannabis Scheme

- Objective to make more quality medicinal cannabis products available
- Increasing supply by allowing domestic cultivation and production
- Increasing access by reviewing prescriber requirements and information needs
- Medicinal Cannabis Advisory Group
- Medicinal Cannabis Agency
- Consultation on details of Scheme and regulatory proposals May/June 2019

# 2020 Cannabis Referendum

- Binding referendum to be held with the 2020 General Election
- To determine whether legislative provisions for the legalisation of cannabis should be adopted
- Current prohibition approach does not deter cannabis use or address the health and social harms it causes
- Proposed regulatory model – Govt-controlled regulated market
- Primary objective to improve well-being by minimising the harm associated with cannabis