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

START

Can it be a CBD product?

Yes

An application for approval to prescribe is not required, if prescribing is within the specified requirements.

Further information about CBD products is available on the Ministry of Health website.

No

Is the product a pharmaceutical grade product?

Yes

Is the product Sativex and is it being used to treat MS symptoms?

Yes

An application for approval to prescribe is not required, if prescribing is within the specified requirements.

Further information about Sativex is available on the Medsafe website.

No

Is consent for distribution available?

Yes

No

Is the product a non-pharmaceutical grade product?

Yes

An application for approval to prescribe is required.

Further information, including the application forms, is available on the Ministry of Health website.

No

Email Medicines Control medicinescontrol@moh.govt.nz

*In New Zealand Sativex is approved for use as an add-on treatment for symptom improvement in patients with moderate to severe spasticity due to Multiple Sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.
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