



Medicinal Cannabis

Current regulations & how to prescribe CBD

Graham Gulbransen

Cannabis Consultant, GP & Addiction Specialist, Henderson

doctor@cannabiscare.nz

PHARMAC Seminar 15 March 2019

'Hi there we are doing fantastically! Keira is on .5ml morning and night and is having less than 12 seizures a week. It has been so great. Child development services and her physiotherapist are amazed at how much of an impact it has had on her she is able to do a lot more like swimming and make eye contact and she is starting to eat food as well as reach out for objects. Every day life has been made a whole lot easier. We are truly thankful that we were given the opportunity to have tilray and see her thrive so much. Thank you once again'



‘...almost everybody knows that cannabis is either essentially harmless or else necessarily toxic.’

Yet, like most arguments, the truth is between these extremes, depending on the ages of use, and frequency and chronicity of use.’

Richard P Mattick,
Drug and Alcohol Review,
July 2017

You may find this presentation

challenging...

1. Is it safe?
2. Is it legal?
3. Is it snake oil?
4. Why haven't we been taught about ECS?
5. Should GPs be recommending herbs?
6. How do GPs recommend/prescribe?
7. Remember medicinal cannabis is here now!

Medical Practitioners

2017 Medicinal Cannabis Course

22 June 2017 Melbourne Crowne Plaza



The First Australian Medicinal Cannabis Course designed for health care practitioners for health care practitioners.

A comprehensive introduction to:

- The Australian history of medicinal cannabis
- The endocannabinoid system
- The pharmacology of cannabinoid medicine
- The practicalities of dosing
- Conditions amenable to treatment
- Up to date literature
- International perspectives
- ...& much more!

Assoc Prof
David Caldicott
Canberra





This is to certify that

Graham Gulbransen

attended the

**MEDICINAL CANNABIS EDUCATION'S
'ESSENTIALS OF MEDICINAL CANNABIS' COURSE**

Saturday 19 and Sunday 20 May 2018

Held at the National Institute of Integrative Medicine, 11-23 Burwood
Rd, Hawthorn, Victoria

The course consisted of 12 hours of educational activities which included:
expert presentations, interactive group learning including case studies, Q&A

MEDICINAL CANNABIS EDUCATION (WWW.MEDICINALCANNABISEUCATION.ORG.AU) IS A CONSORTIUM OF THE NATIONAL INSTITUTE OF INTEGRATIVE MEDICINE, THE AUSTRALASIAN COLLEGE OF NUTRITIONAL AND ENVIRONMENTAL MEDICINE AND THE NATIONAL INSTITUTE OF COMPLEMENTARY MEDICINE

Definitions



- Adult use (Recreational)
- Therapeutic
- Medicinal

Cannabis plant



- Thousands of strains – like tomatoes, grapes, apples etc!
- THC & CBD main active compounds
- Continuum from
 - THC dominant → euphoriant, intoxicant, therapeutic
 - Balanced THC/CBD → therapeutic
 - CBD dominant → therapeutic

BEDROCAN®



Bedrocan is featuring 22% THC, with a CBD-level below 1%.

BEDROBINOL®



Its THC-level is standardised at 13.5%, with a CBD-level below 1%.

BEDIOL®



Bediol has a balanced ratio of THC 6.3% and CBD 8%.

BEDICA®



Bedica contains 14% THC with less than 1% CBD.

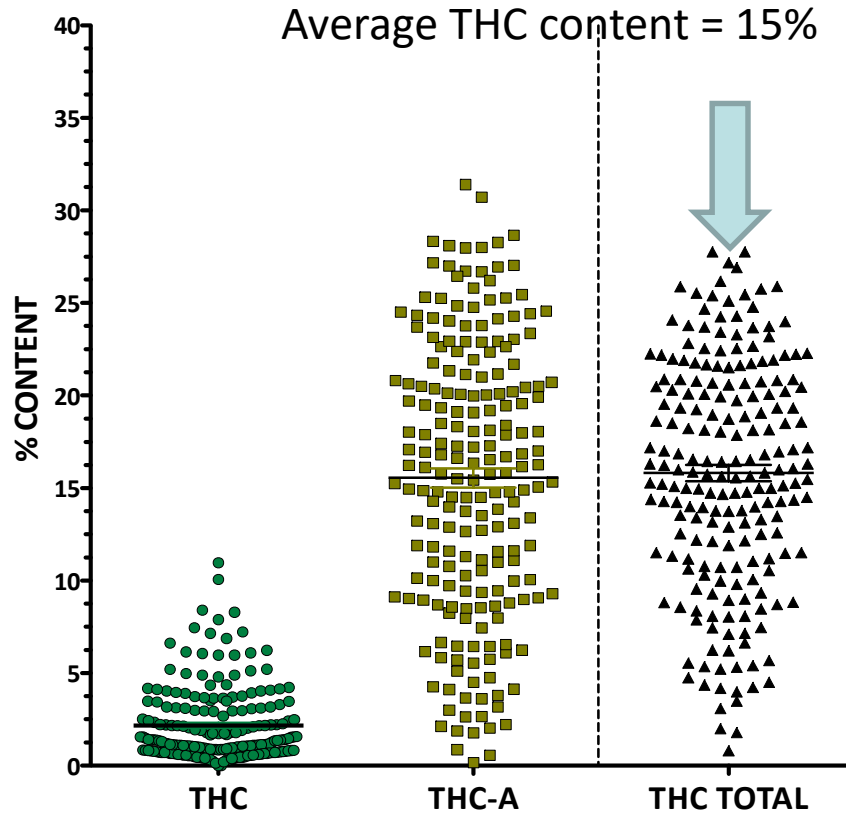
BEDROLITE®



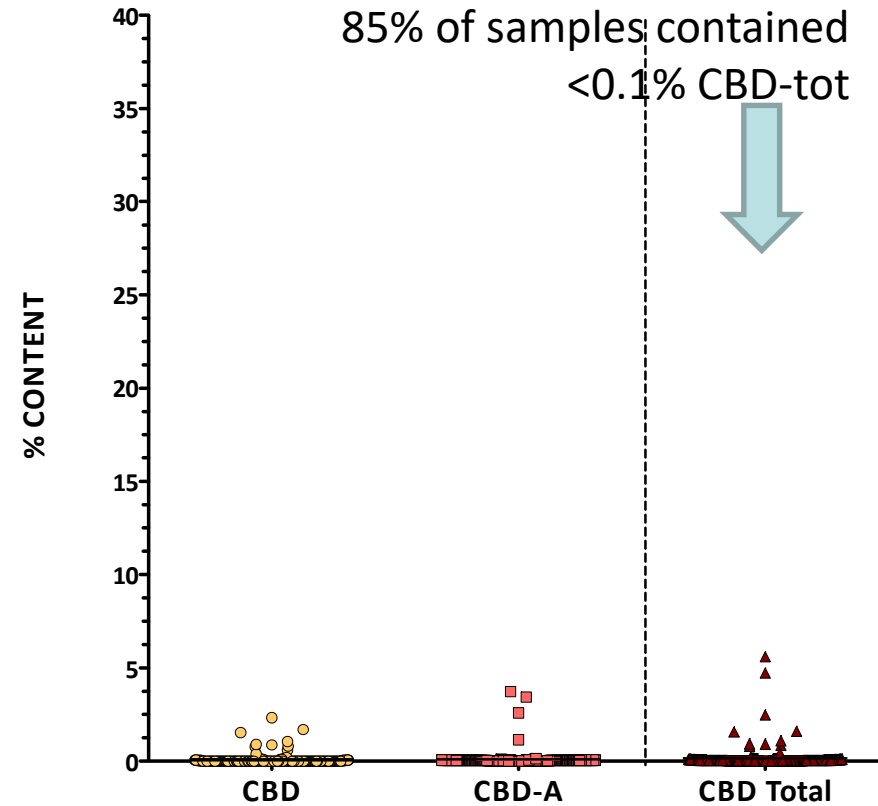
Bedrolite is a CBD-only product, with less than 1% THC and 9% CBD.

Potency of NSW police seized cannabis: high THC and low CBD

Swift et al PLoS One 2013



THC: psychoactive, sedation, analgesia, antiemesis, antispasmodic



CBD: anxiolytic, antipsychotic, anticonvulsant, protective against memory loss

T₁ H₄ C₃

C₃ B₃ D₂

T₁ H₄ C₃ V₄

C₃ B₃ N₁

C₃ B₃ D₂ V₄

C₃ B₃ C₃

Phytocannabinoids

>140 cannabinoids in cannabis plant. Most non-psychoactive.

Each cannabinoid has its own pharmacological actions and therapeutic potential.

Plus ... terpenes

“Entourage” effects: whole plant vs single molecules



OTHER COMPONENTS

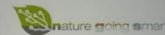
- ▶ 120 terpenes
- ▶ 50 hydrocarbons
- ▶ 34 sugars
- ▶ 20 alkaloids
- ▶ 19 flavonoid-glycosides
- ▶ 16 phenols
- ▶ 13 ketones
- ▶ 12 aldehydes
- ▶ 11 steroids
- ▶ 7 alcohols
- ▶ 2 pigments

> 500



CANNABIS RESEARCH
ONE PLANT. MANY MOLECULES

Viola Brugatelli
Founder & Chief Editor

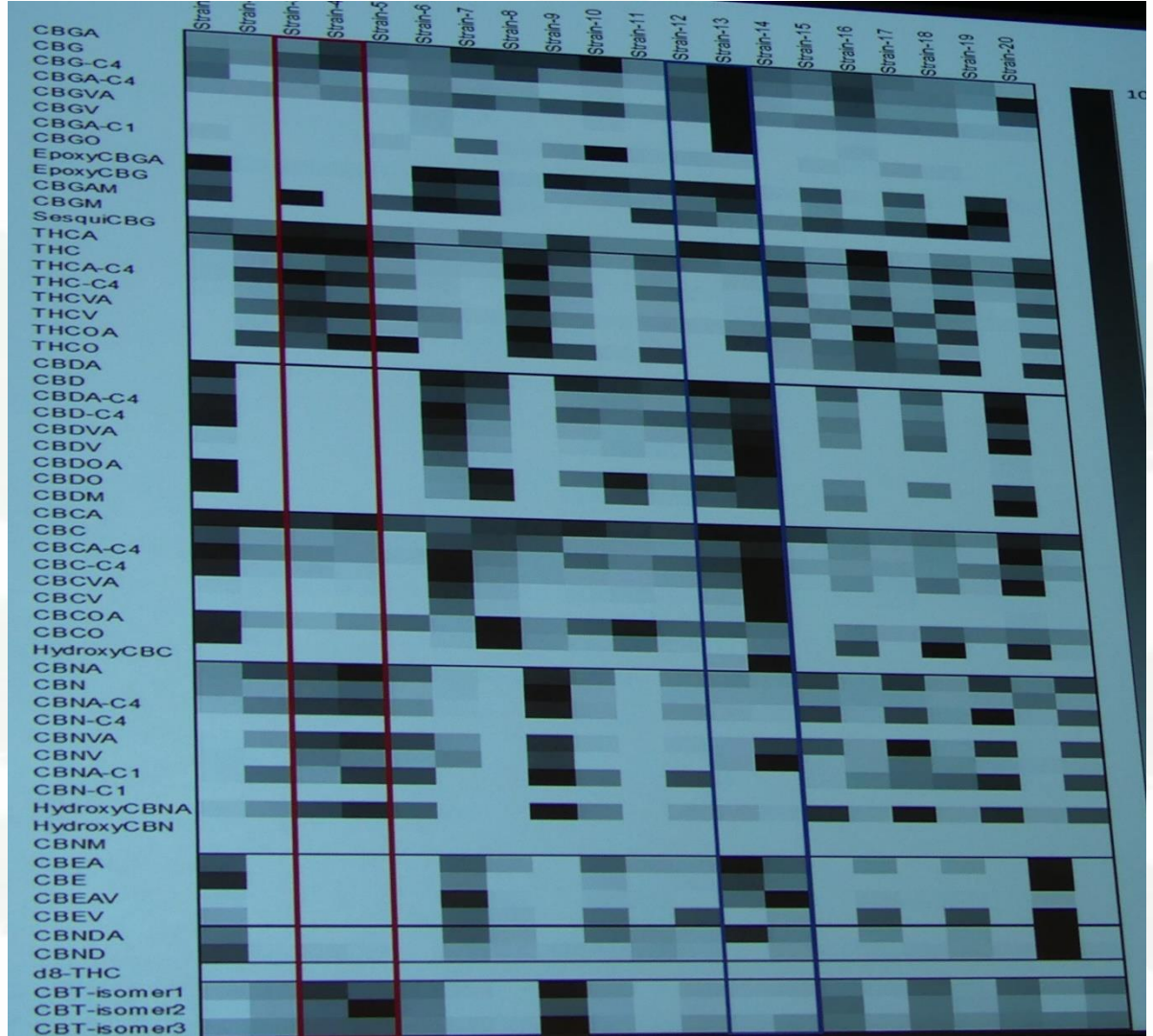


Terpenes

From Epilepsy Action Australia
www.epilepsy.org.au

α -PINENE	Pine Needles	Anti-bacterial Anti-fungal Anti-inflammatory Bronchodilator Aids short term memory
B-CARYOPHYLLENE	Black Pepper Clove Hops	Anti-bacterial Anti-cancer Anti-fungal Anti-inflammatory Anti-septic
BORNEOL	Camphor	Analgesic Anti-insomnia Anti-septic Bronchodilator
CARYOPHYLLENE OXIDE	Eucalyptus	Anti-fungal Anti-ischemic
CINEOL	Tea tree	Anti-bacterial Anti-depressant Anti-inflammatory Anti-ischemic Bronchodilator
CITRONELLOL	Rose	Anti-cancer Anti-inflammatory Anti-insomnia Anti-spasmodic

HUMULENE	Hops	Anorectic Anti-cancer Anti-bacterial Anti-inflammatory
LIMONENE	Citrus	Anti-anxiety Anti-bacterial Anti-cancer Anti-depressant Anti-fungal
LINALOOL	Lavender	Anti-anxiety Anti-bacterial Anti-depressant Anti-insomnia
MYRCENE	Lemongrass Mango	Analgesic Anti-cancer Anti-inflammatory Anti-insomnia Anti-spasmodic
NEROLIDOL	Wood Citrus rind	Anti-fungal Anti-insomnia
PHYTOL	Green tea	Anti-insomnia
TERPINOLENE	Lilac Apple	Anti-bacterial Anti-fungal Anti-insomnia Anti-septic



Medicinal cannabis is NOT usually smoked as a joint

- Taken orally as drops, lozenges, capsules
- Oral spray
- Inhaled with vaping devices (non-combustion)
- Topical balms.



‘I don’t want to get high’

‘I just want relief from pain, nausea, insomnia, anxiety etc’

CBD is non-euphoriant, but widely therapeutic, few adverse effects

CBD Good News – Bad News

- All registered medical practitioners may prescribe CBD for any condition
- Chronic pain and/or emotional distress is a good place to start
- CBD not in Mims, NZF – add manually.

Products containing THC

- Products containing THC generally require Specialist Application to MoH
- Regulations appear unnecessarily complicated.

Evidence



- Abundant evidence supporting medicinal cannabis
- Ask your patients what they use and the outcome.

Other concerns



- Psychosis/Schizophrenia
 - Most unlikely with adult-use and nil to low THC
- Addiction
 - Most unlikely with CBD products
 - No figures for medicinal use
- Children
 - CBD safe, THC may be appropriate for severe conditions.

Cannabis Use 2012/13: New Zealand Health Survey

Published online: 28 May 2015

Summary

The 2012/13 New Zealand Health Survey (NZHS) provides valuable information about cannabis use by adults aged 15 years and over. It builds upon and adds value to the findings of the 2007/08 New Zealand Alcohol and Drug Use Survey report on cannabis.

This report presents information on cannabis use in New Zealand, including patterns of use, drug-driving, harms from use (productivity and learning, and mental health), legal problems, and cutting down and seeking help. Information on the medicinal use of cannabis is also presented.



New Zealand Health Survey 2012/2013, which sampled 13,009 people, aged 15+ years

<https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2016/vol-129-no-1433-22-april-2016/6865>

<http://www.health.govt.nz/publication/cannabis-use-2012-13-new-zealand-health-survey>

Patterns of cannabis use

- Eleven percent of adults aged 15 years and over reported using cannabis in the last 12 months (defined here as cannabis users). Cannabis was used by 15% of men and 8.0% of women. Māori adults and adults living in the most deprived areas were more likely to report using cannabis in the last 12 months. Thirty-four percent of cannabis users reported using cannabis at least weekly in the last 12 months. Male cannabis users were more likely to report using cannabis at least weekly in the last 12 months.

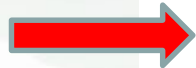
Cannabis use for medicinal purposes

- Forty-two percent of cannabis users reported medicinal use (ie, to treat pain or another medical condition) in the last 12 months. Rates were similar for men and women. Older cannabis users (aged 55+ years) reported higher rates of medicinal use.

Telephone survey

Latest 2018 results

	Illegal	Decriminalise	Legal	Decriminalise/legalise
Personal possession	31%	32%	35%	67%
Personal growing	38%	29%	32%	61%
Growing for friends	69%	18%	12%	30%
For pain relief	13%	17%	70%	87%
For terminal pain relief	10%	17%	72%	89%
Selling from a store	60%	9%	29%	38%



Published 24 July 2018

Biological Plausibility: ECS

- There's a reason cannabis works:
 - The Endocannabinoid System
- 'Neuro-immuno homeostasis signalling system'
- Present in all vertebrates, in most animals from sea squirts to humans
- **Cannabinoid receptors are present throughout the body, embedded in cell membranes, and are believed to be more numerous than any other receptor system.**

Viola Brugnatelli - Neuroscientist

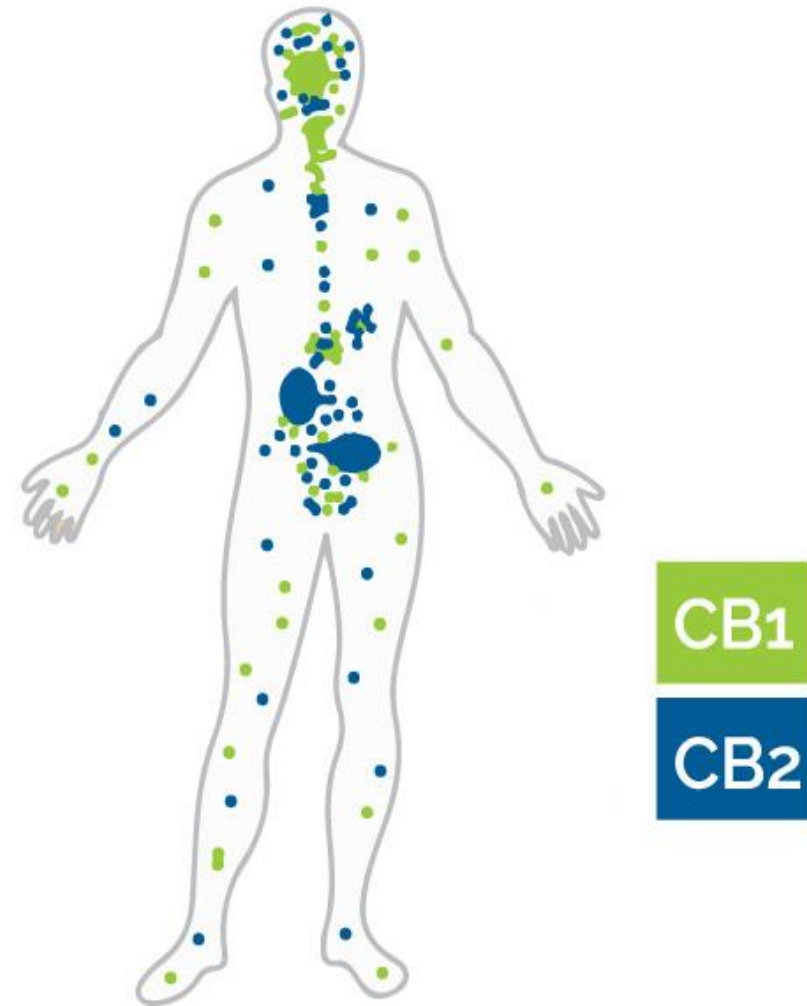
Hemp Expo Sydney May 2017 &

<https://naturegoingsmart.com/understanding-endocannabinoid-system/>

Endocannabinoid System - ECS

Homeostasis

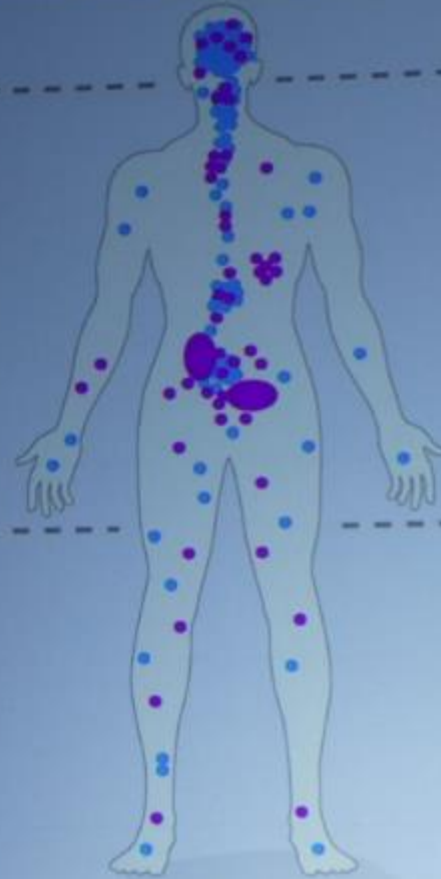
- CB1 receptors:
 - Brain: cortex, basal ganglia, hippocampus, cerebellum
 - Modulate: memory, mood, executive function, cognition, analgesia, movement
 - GI: appetite, lipolysis
 - Respiratory
- CB2 receptors
 - Immune system: regulate inflammation, neuropathic pain
- CB3 & other receptors under investigation



Regulates Many Physiological Processes

NEURAL DEVELOPMENT
NEUROPROTECTION
MOVEMENT
PSYCHOMOTOR BEHAVIOUR
PAIN

CARDIOVASCULAR
IMMUNE FUNCTION
METABOLISM
APPETITE REGULATION



STRESS
EMOTION
MEMORY
COGNITION
SLEEP

DIGESTION
INFLAMMATION
THERMOREGULATION



EAT



SLEEP



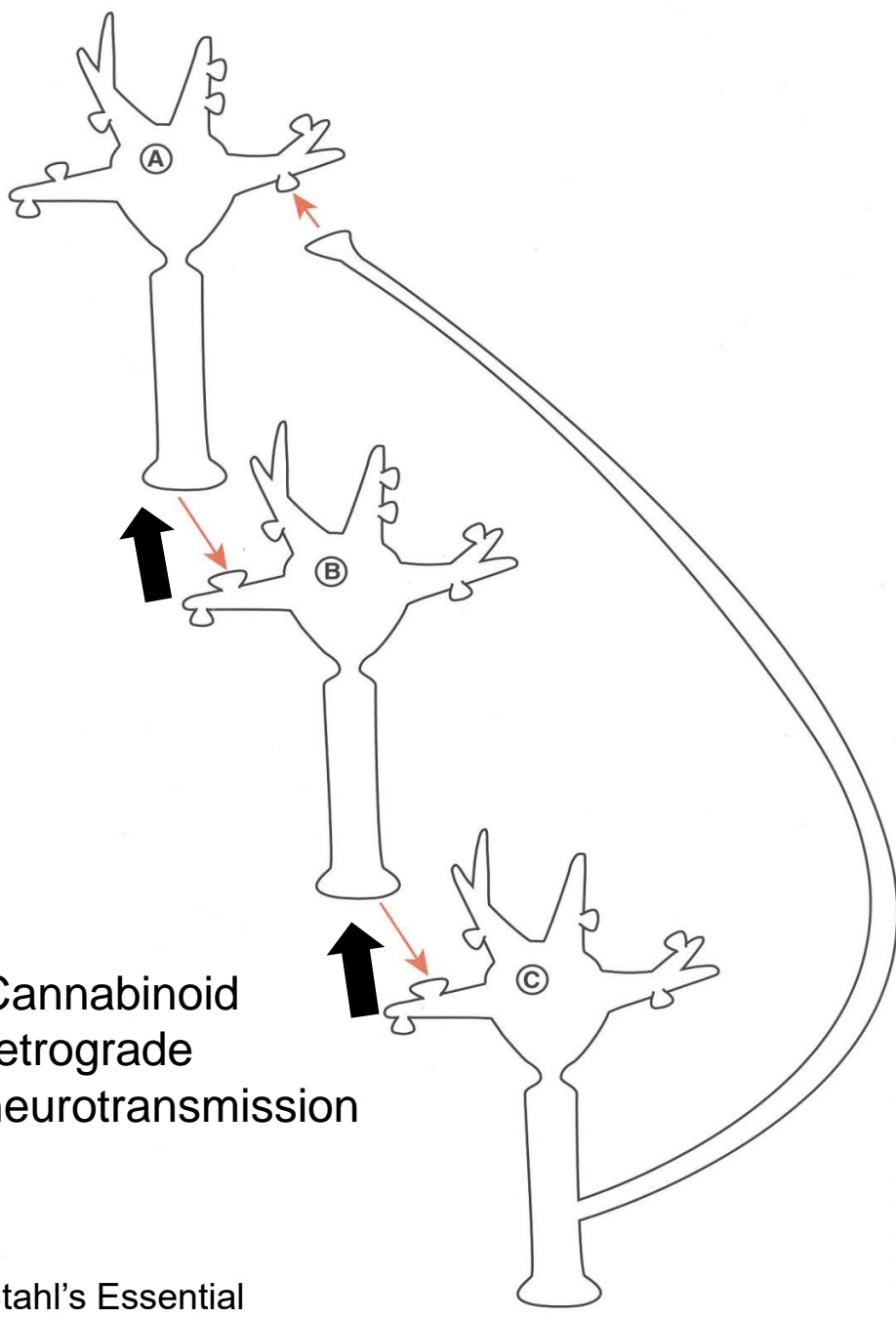
RELAX



FORGET

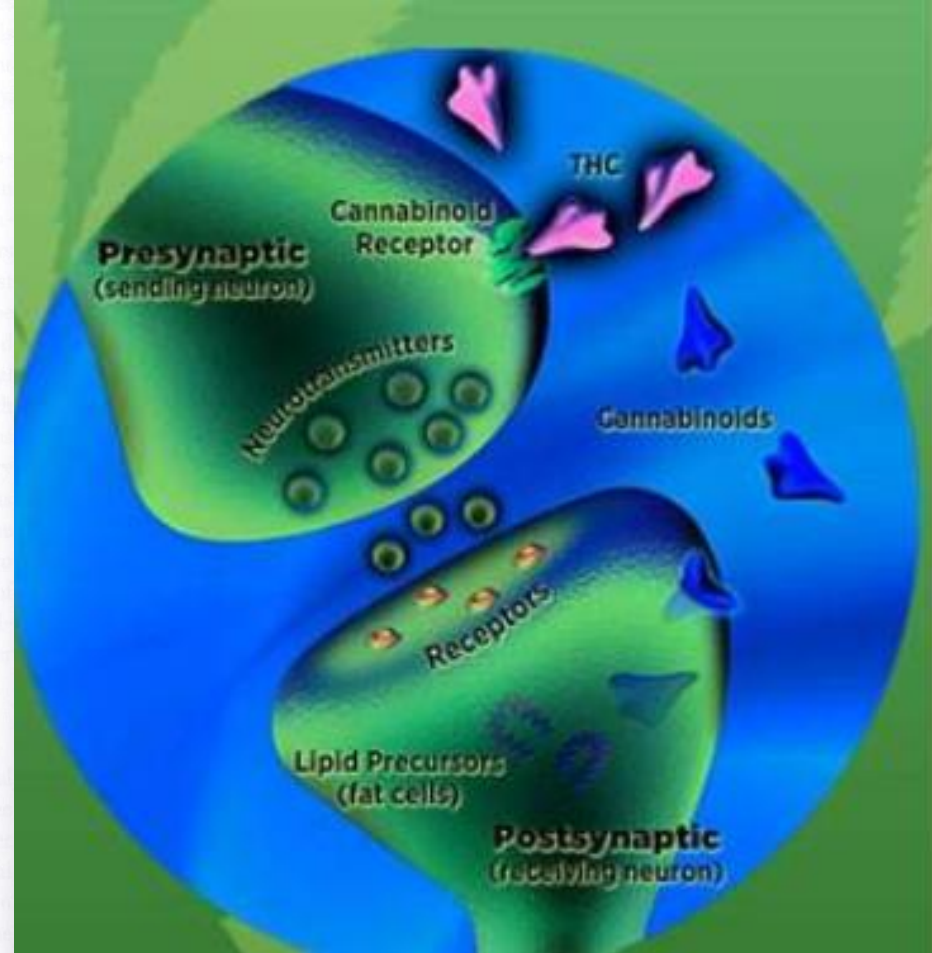


PROTECT



Cannabinoid retrograde neurotransmission

Stahl's Essential Psychopharmacology, 2008, p56



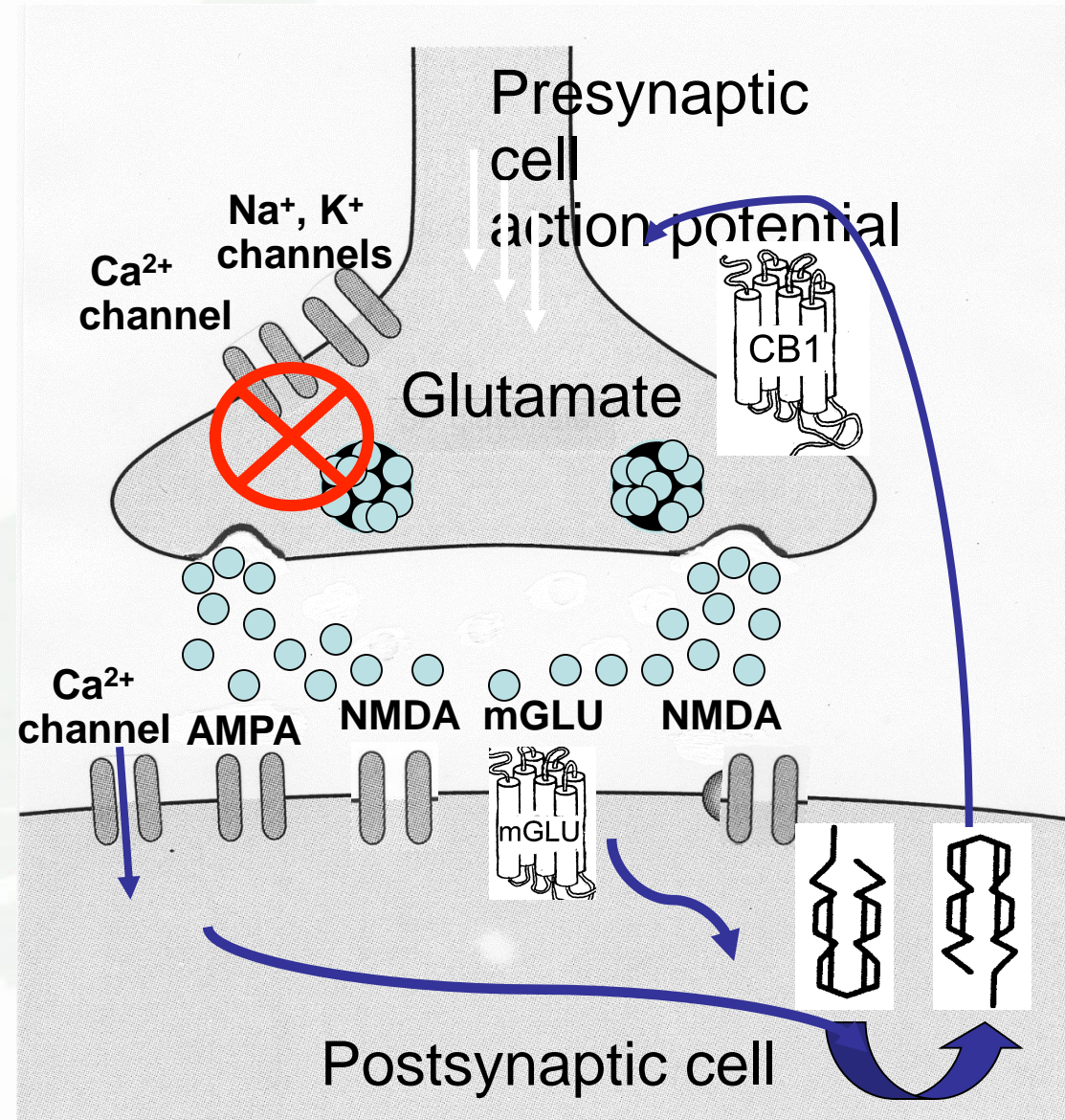
Viola Brugnattelli, neuroscientist, <https://naturegoingsmart.com/understanding-endocannabinoid-system/> 2017

Cannabinoids regulate neurotransmission

- Pain
- Epilepsy
- Anxiety, PTSD

Depolarization-Induced Suppression of Excitation

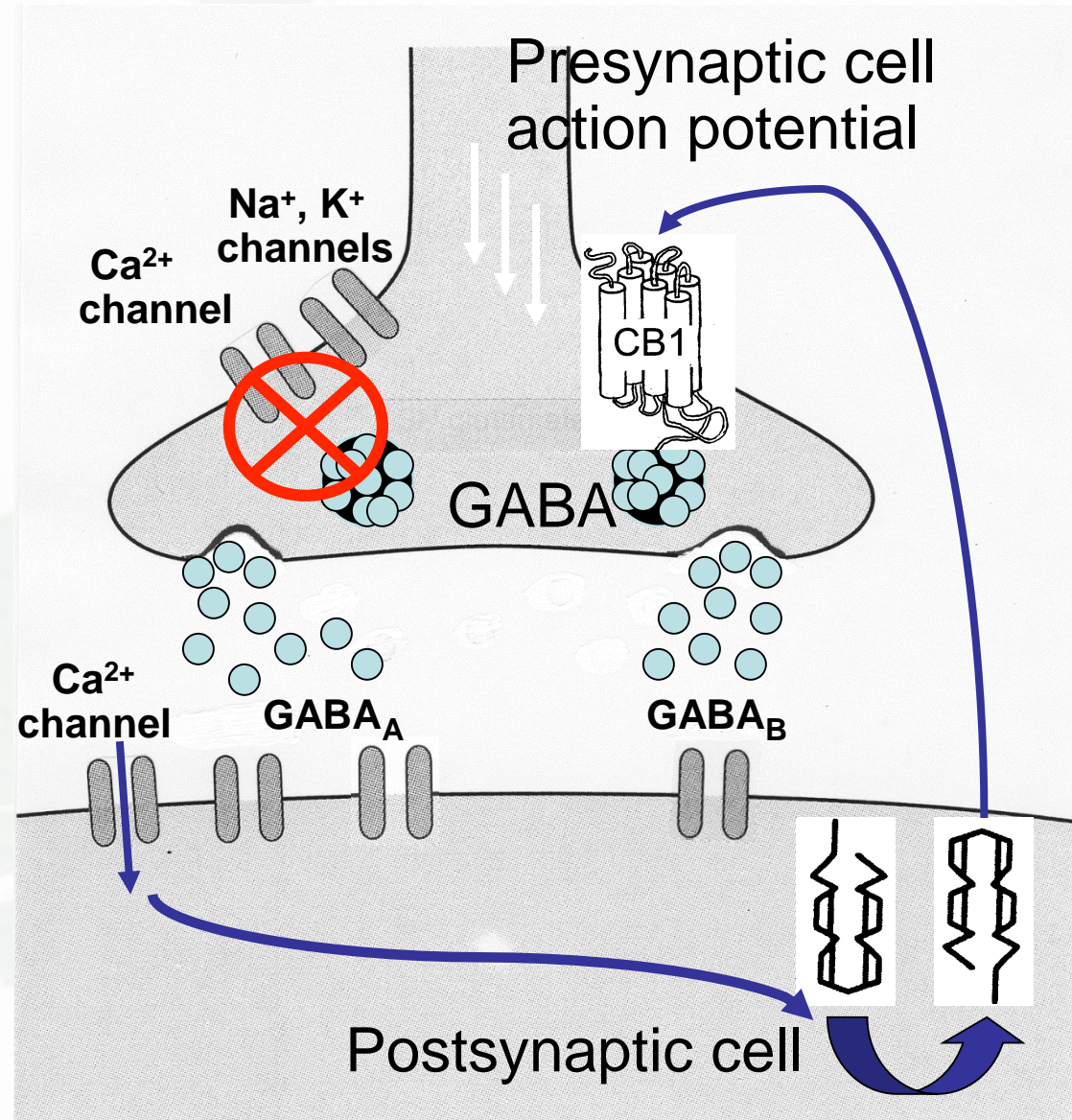
- Ca^{2+} influx into post-synaptic cell stimulates the synthesis and release of 2-AG.
- 2-AG diffuses retrograde to presynaptic CB_1 , which closes pre-synaptic Ca^{2+} channels and stops vesicle release.



(Wilson & Nicholl, 2002)

Depolarization-Induced Suppression of *Inhibition*

- Ca^{2+} influx into post-synaptic cell stimulates the synthesis and release of 2-AG.
- 2-AG diffuses retrograde to presynaptic CB_1 , which closes pre-synaptic Ca^{2+} channels and stops vesicle release



Clinical endocannabinoid deficiency (CECD) revisited: can this concept explain the therapeutic benefits of cannabis in migraine, fibromyalgia, irritable bowel syndrome and other treatment-resistant conditions?

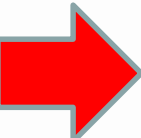
Smith SC, Wagner MS.

Abstract

OBJECTIVES: Ethan B. Russo's paper of December 1, 2003 explored the concept of a clinical endocannabinoid deficiency (CECD) underlying the pathophysiology of migraine, fibromyalgia, irritable bowel syndrome and other functional conditions alleviated by clinical cannabis.

METHODS: Available literature was reviewed, including searches via the National Library of medicine database and other sources.

RESULTS: A review of the literature indicates that significant progress has been made since Dr. Ethan B. Russo's landmark paper, just ten years ago (February 2, 2004). Investigation at that time suggested that cannabinoids can block spinal, peripheral and gastrointestinal mechanisms that promote pain in headache, fibromyalgia, irritable bowel syndrome and muscle spasm.



CONCLUSION: Subsequent research has confirmed that underlying endocannabinoid deficiencies indeed play a role in migraine, fibromyalgia, irritable bowel syndrome and a growing list of other medical conditions. Clinical experience is bearing this out. Further research and especially, clinical trials will further demonstrate the usefulness of medical cannabis. As legal barriers fall and scientific bias fades this will become more apparent.

Introduction



Jeffrey Y. Hergenrather, MD

General practice physician

Solo private practice

Cannabis consultations since 1997

Sebastopol, California

SOCIETY *of*
CANNABIS
CLINICIANS

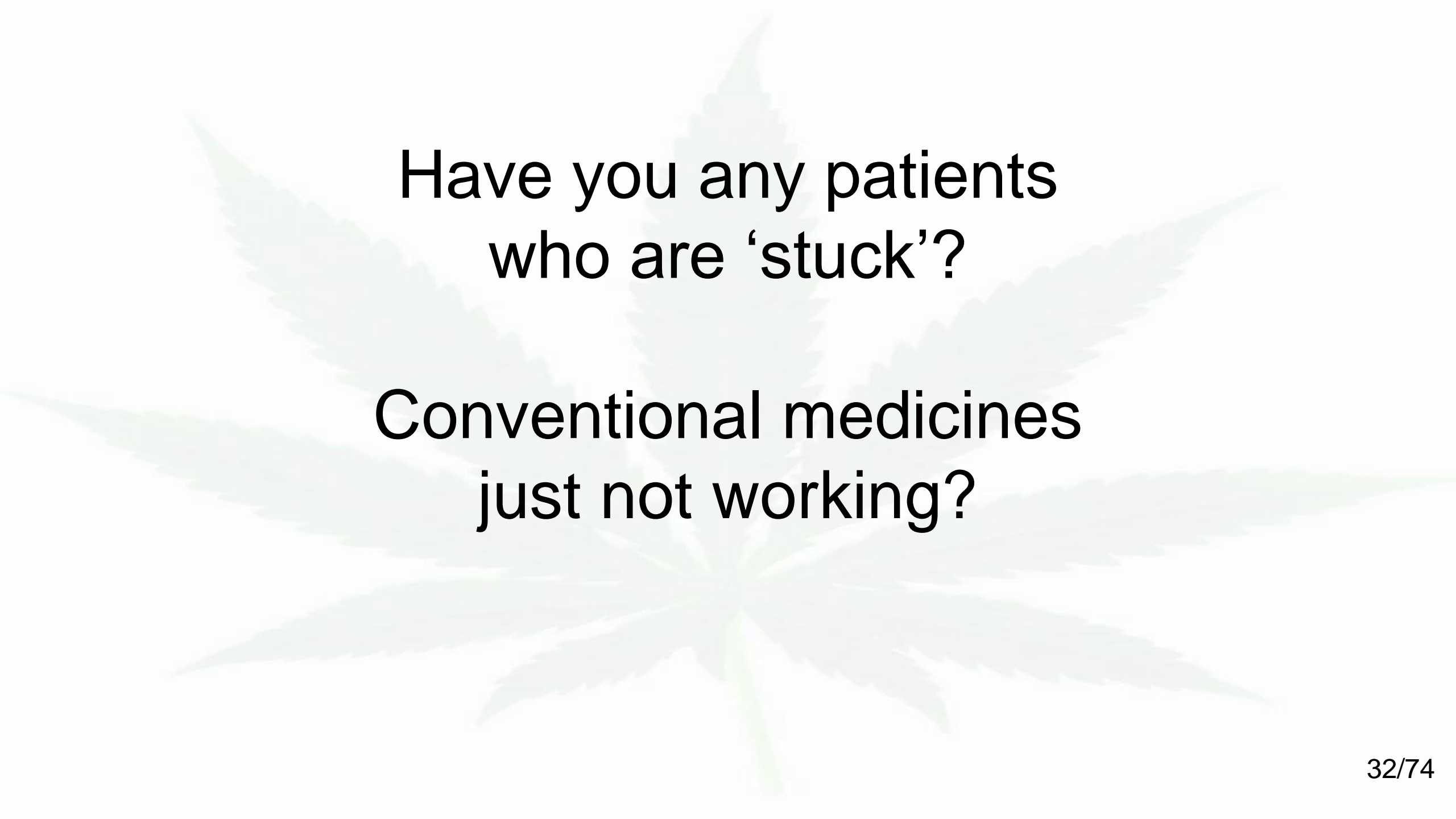
President and founding member of
The Society of Cannabis Clinicians

I have no financial relationships to disclose.

Conditions in Clinical Practice

Rank order - Hergenrather 2017

- Pain (acute pain, chronic inflammatory, neuropathic)
- Mental disorders (all kinds)
- Cancers
- Gastrointestinal disorders
- Insomnia
- Migraine headaches
- Harm reduction, alternative to opioids . . .
- Spastic disorders
- Autoimmune disorders
- Neurodegenerative disorders
- Glaucoma
- Skin diseases
- Epilepsy, Autism, Tourettes, ADD, Dystonia, Dementia
- AIDS and other infections



Have you any patients
who are 'stuck'?

Conventional medicines
just not working?

Classification of Controlled Drugs

Class A drugs pose a very high risk of harm

- eg heroin; methamphetamine

Class B drugs pose a high risk of harm

- Class B1: eg. morphine; opium; **cannabis oil**
- B2: eg. methylphenidate; amphetamine
- B3: eg. fentanyl; pethidine

Class C drugs pose a moderate risk of harm

- C1: eg. **cannabis plant**; Catha edulis plant (Khat)
- C2: eg. codeine; dihydrocodeine
- C3: eg. pholcodine
- C4: eg. buprenorphine; barbiturates (no longer prescribed)
- C5: eg. benzodiazepines; phenobarbitone; ephedrine; pseudoephedrine
- C6: eg. codeine/paracetamol; (mixtures of class C drugs with other substances)

Section 29 medicines are considered 'new' medicines because they do not have a consent for distribution and advertising of such medicines is prohibited under section 20 of the Medicines Act.

20 Restrictions on sale or supply of new medicines

(1) Except as provided in [sections 25](#), [26\(4\)](#), [28](#), [30](#), [31](#), and [32](#), this section applies to new medicines.

(2) **No person shall—**

(a) sell; or

(b) distribute by way of gift or loan or sample or in any other way; or

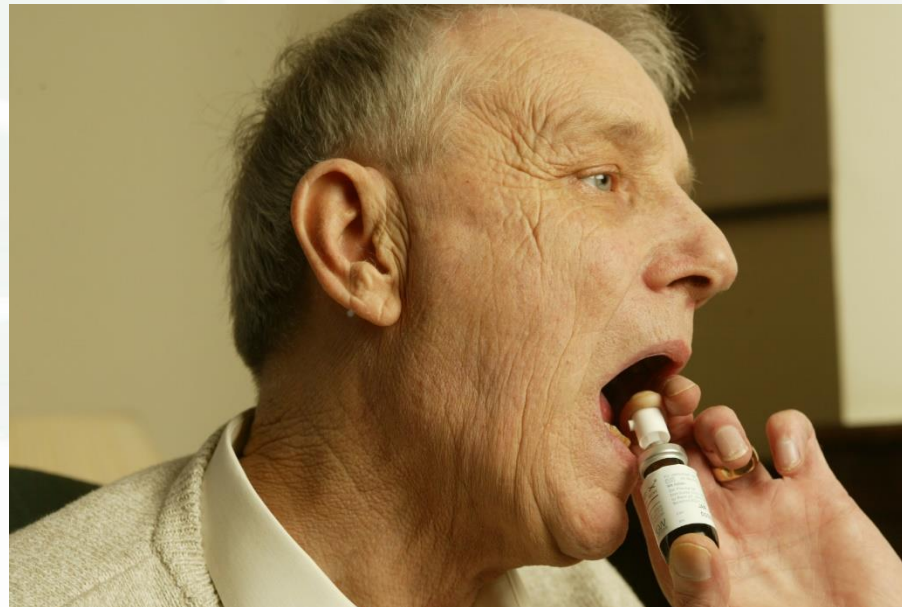
(c) **advertise the availability of—**

any medicine to which this section applies before the consent or provisional consent of the Minister to the distribution of the medicine has been notified in the *Gazette*, or otherwise than in accordance with such conditions as may be imposed by the Minister on giving his consent or provisional consent and notified in the *Gazette*.

Reminder: Patient consent needed for Section 29 prescriptions

Six Pathways to medicinal cannabis

<https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis/prescribing-cannabis-based-products#3>



Prescribing medicinal cannabis

1. CBD products

2. Sativex – Approved condition

3. Sativex – Unapproved use

4. Pharmaceutical grade cannabis-based product without consent for distribution

5. Non-pharmaceutical grade

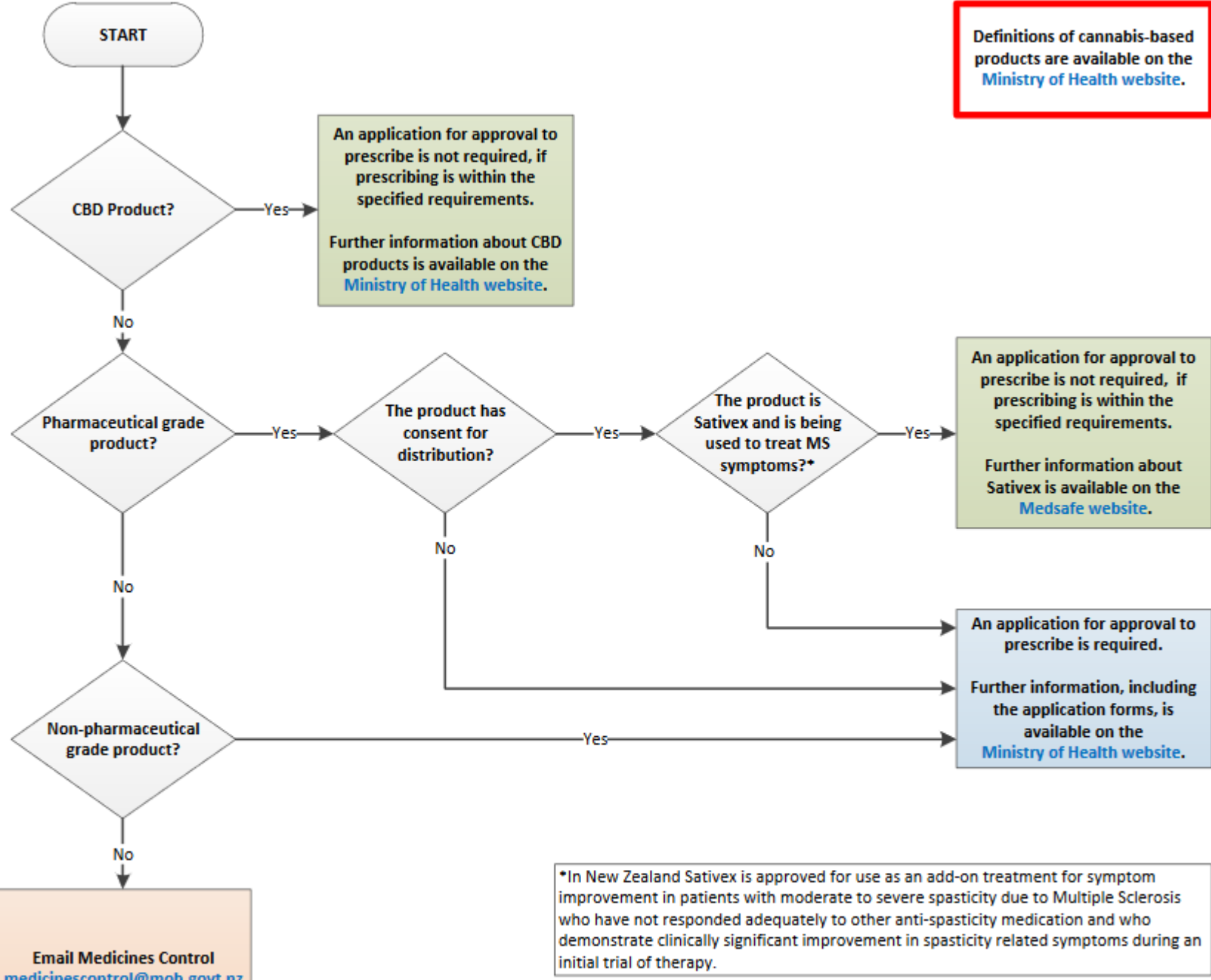
6. Compassionate cannabis

Summary of Approvals Required to Prescribe Cannabis Based Products

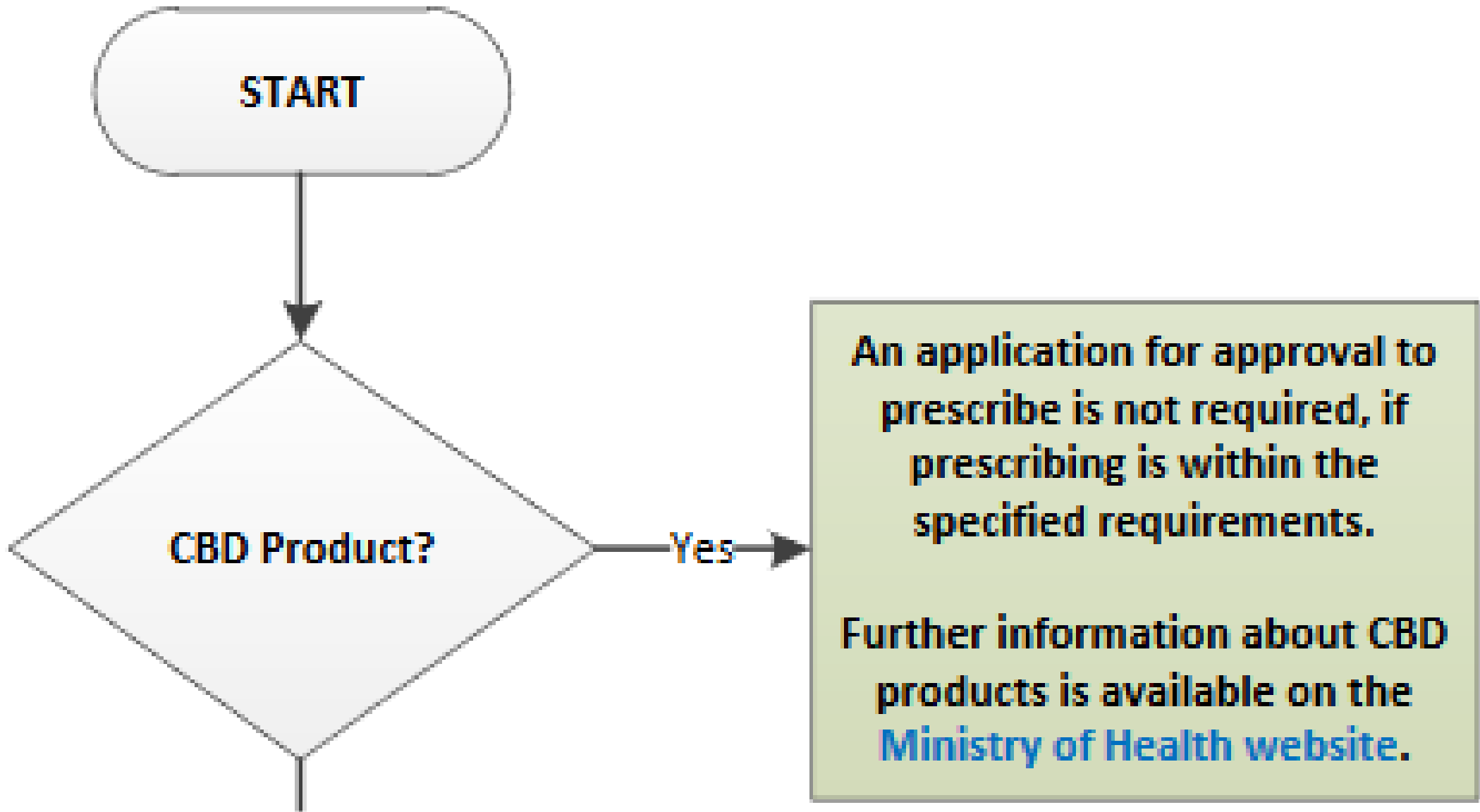


7 September 2017

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



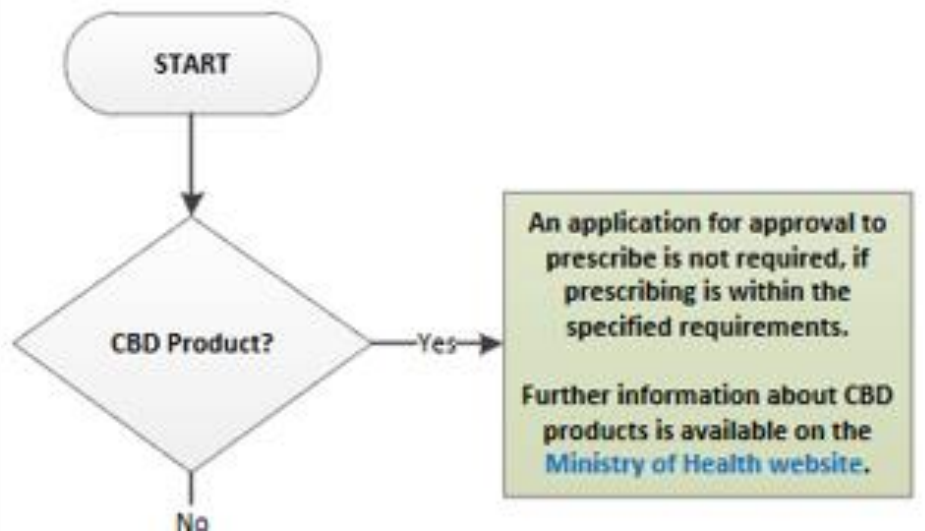
*In New Zealand Sativex is approved for use as an add-on treatment for symptom improvement in patients with moderate to severe spasticity due to Multiple Sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity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



1. Cannabidiol CBD

‘In practical terms the changes mean CBD would be able to be prescribed by a doctor to their patient and supplied in a manner similar to other prescription medicine.’

Peter Dunne, Associate Minister of Health, 2/6/17.



These regulations, which came into force on 7 September 2017, amend the Misuse of Drugs Regulations 1977

- Most of the amendments apply in respect of products that contain cannabidiol but do not contain, or contain only small quantities of, other cannabinoids usually found in cannabis (*CBD products*)

[if it contains other cannabinoids usually found in cannabis, contains those cannabinoids in a quantity that, in total, constitutes no more than 2% of the total quantity of cannabinoids in the product.] **ie must be 98% CBD**

Those amendments—

- allow a medical practitioner, a person who holds a licence to operate a pharmacy under the [Medicines Act 1981](#), or a person who holds a licence to deal in controlled drugs under the Act to import a CBD product without a licence to import the product and to possess and supply that CBD product:
- allow CBD products to be supplied, administered, or prescribed **without** the approval of the Minister of Health:

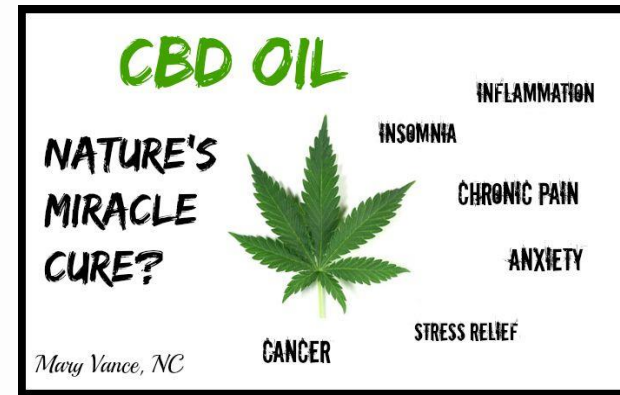
Those amendments (continued) —

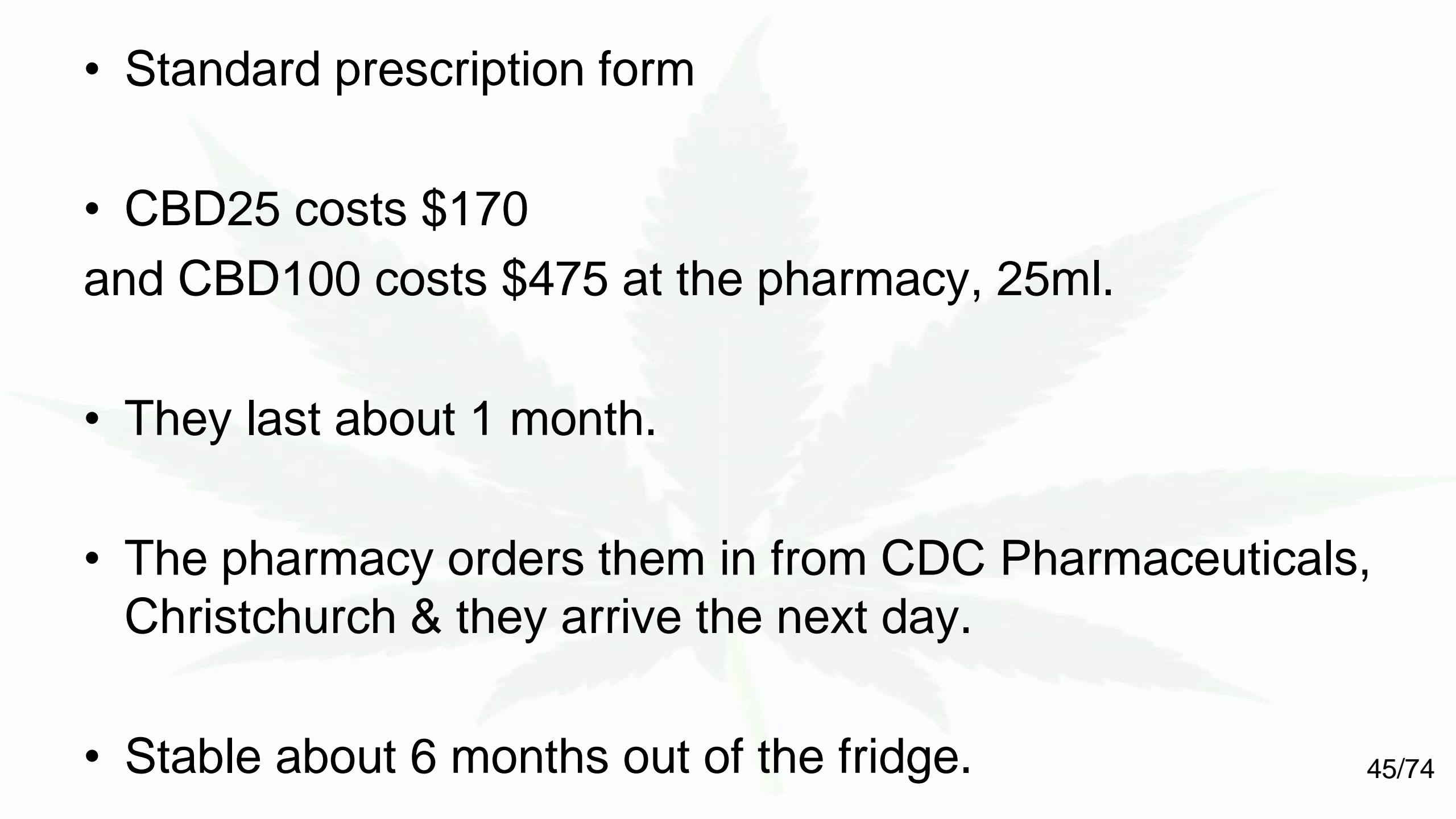
- except CBD products from the **storage** requirements that apply to other controlled drugs:
- except prescriptions for CBD products from the requirement to be on an approved **form** that applies to prescriptions for other controlled drugs:
- allow CBD products to be prescribed in a quantity sufficient for use for a period of 3 months:
- except CBD products from the requirements of **Part 6** of the principal regulations (which relate to record keeping and returns).

Cannabidiol (CBD)

- **A non-intoxicating cannabinoid**
 - Anticonvulsant effects
 - Anxiolytic, antipsychotic
 - Neuroprotective: ?dementia
 - Analgesia: THC+CBD > THC or CBD alone; synergistic
- Hepatic metabolism:
 - CYP 3A4, 2D9 inhibition: ?clinically relevant
- Doses:
 - ?200-1200mg oral / day prescribed
 - 10-50mg oral / day OTC for 'wellness'

–Graham Gulbransen
experience **50mg bid.**



- 
- Standard prescription form
 - CBD25 costs \$170
and CBD100 costs \$475 at the pharmacy, 25ml.
 - They last about 1 month.
 - The pharmacy orders them in from CDC Pharmaceuticals,
Christchurch & they arrive the next day.
 - Stable about 6 months out of the fridge.

Standard Prescription

Dr Graham Gulbransen

FRNZCGP FACHAM

A4

NZMC: 11258 HPI: 14aefa

CANNABIS CARE CLINIC & ADDICTION TREATMENT, West Care Speci:

Phone: 09 836 9331 Fax: 836 9332

*Pharmacy
Only Use
Item Count*

Prescription
Subsidy Card

Y / N

Pharmacy Stamp

Mr Mouse Mickey

Apartment 99
235 Dominion Road

Mt Eden

Central Auckland Ph: 838 9099

Date of Birth: 12/05/1980 NHI: ABC1235

Disp/ Date Repeat/ Inits

Rx: **Tilray CBD25 drops**

Take 0.25ml at night and increase dose as directed. Contact person is: Mickey 021 234 567
25 ml

Standard Prescription

Dr Graham Gulbransen

FRNZCGP FACHAM

A4

NZMC: 11258 HPI: 14aefa

CANNABIS CARE CLINIC & ADDICTION TREATMENT, West Care Speci:

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Central Auckland Ph: 838 9099

Date of Birth: 12/05/1980 NHI: ABC1235

Disp/ Date Repeat/ Inits

Rx: **Tilray CBD100 drops**

Take 0.25ml at night and increase dose as directed. Contact person is: Mickey 021 234 567
25 ml

Tilray CBD oil has been available in NZ since 7/12/17

19/03/2018

Dr Graham Gulbransen



19/03/2018

Dr Graham Gulbransen



Cannabis Oil Drops Titration Example*

Day	Morning (mL)	Evening (mL)	Total Daily Dose (mL)
1 - 3	0	0.25	0.25
4 - 6	0.25	0.25	0.5
7 - 9	0.25	0.5	0.75
10 - 12	0.5	0.5	1
13 - 15	0.5	0.75	1.25
16 - 18	0.75	0.75	1.5
19 - 21	0.75	1	1.75

↓ **

To be filled out by patient:

My optimal dose is _____ mL/day, taken (when/how often) _____

CBD Adverse Effects



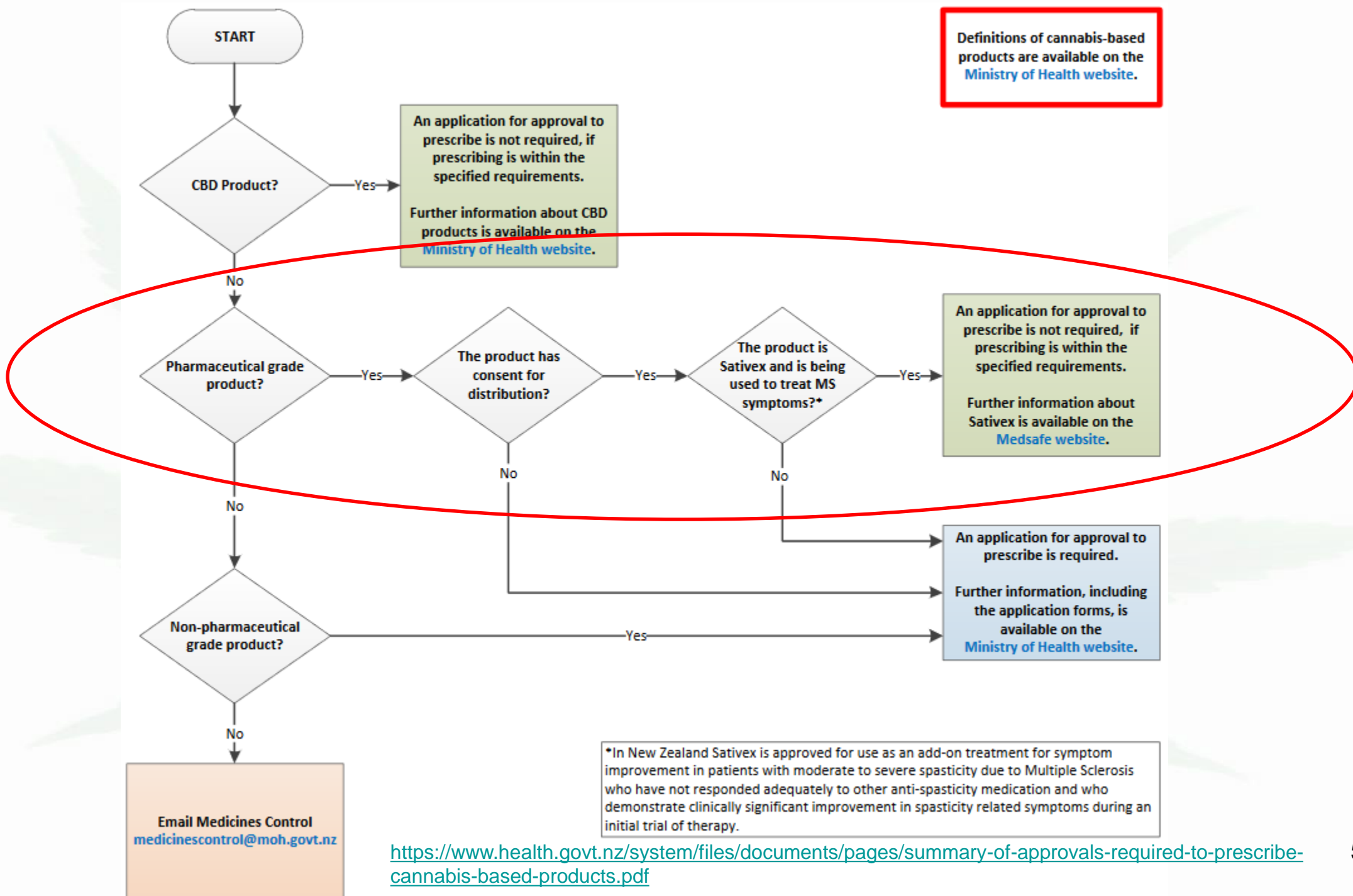
About 10% report minor

- drowsiness
- vivid dreams
- light headedness
- slight diarrhoea
- mouth irritation
- (Financial toxicity...)

CBD Drug-Drug Interactions



- Very unlikely in practice
- Clobazam levels may increase
- Ketoconazole
- Warfarin, monitor INR
- Domperidone?



Definitions of cannabis-based products are available on the Ministry of Health website.

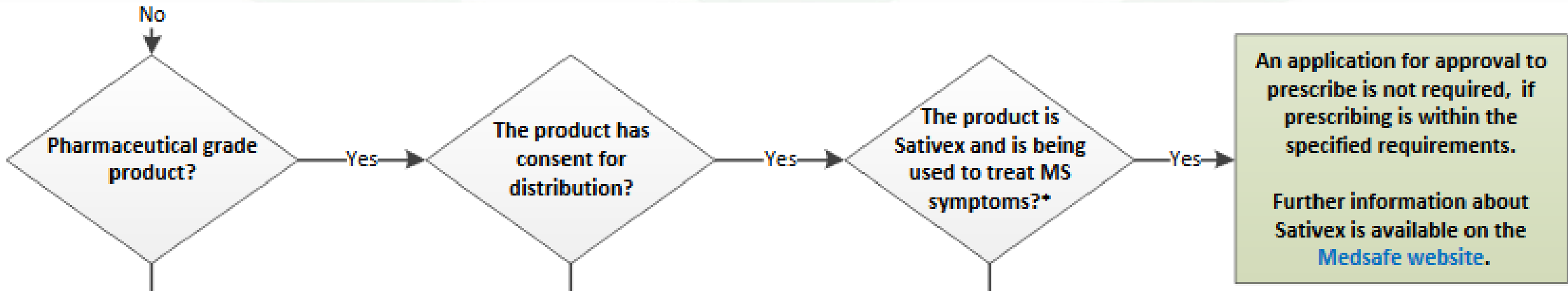
An application for approval to prescribe is not required, if prescribing is within the specified requirements. Further information about CBD products is available on the Ministry of Health website.

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.

An application for approval to prescribe is required. Further information, including the application forms, is available on the Ministry of Health website.

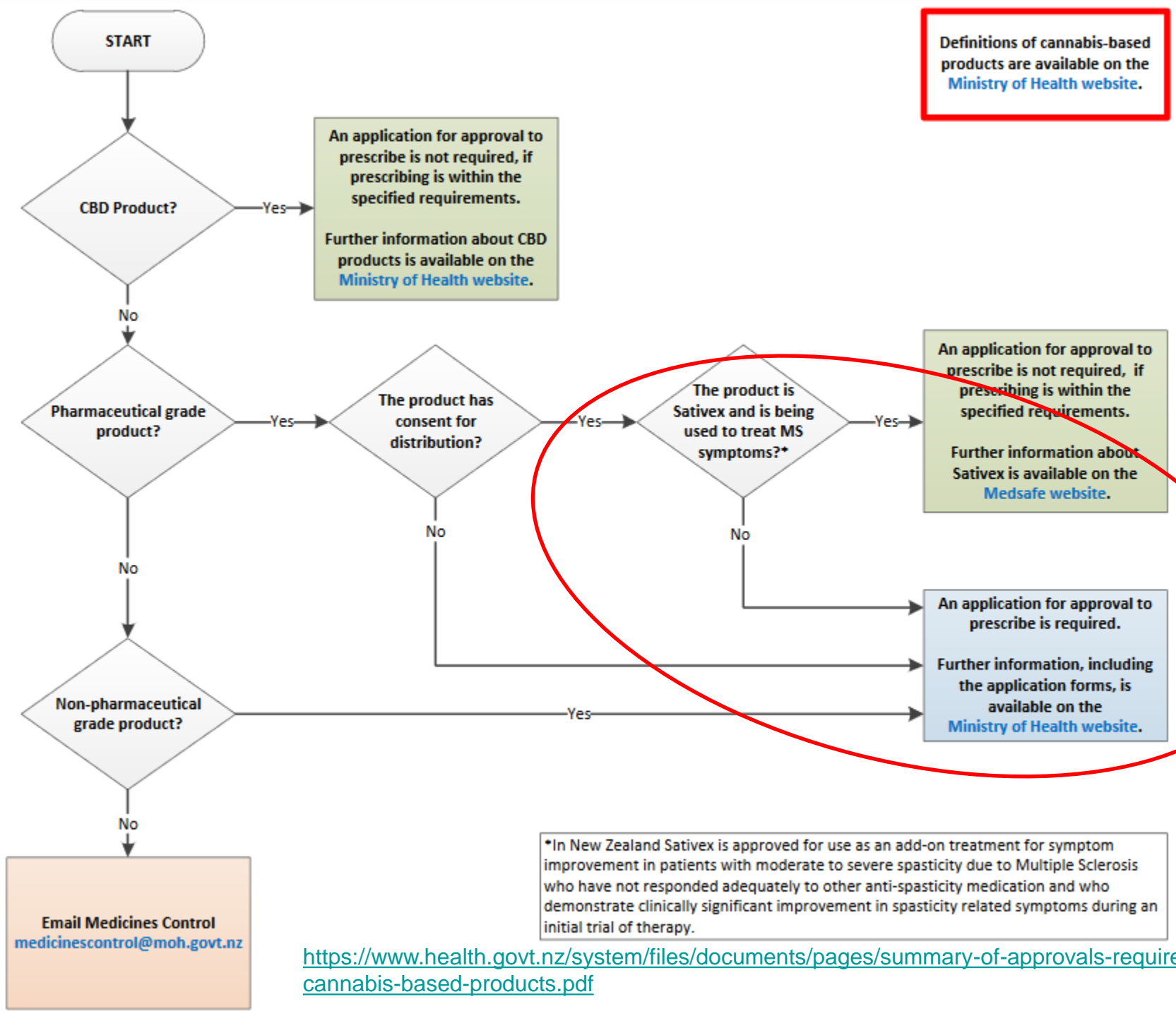
*In New Zealand Sativex is approved for use as an add-on treatment for symptom improvement in patients with moderate to severe spasticity due to Multiple Sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity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

Email Medicines Control
medicinescontrol@moh.govt.nz



2. Restriction on the Supply of Sativex—Approval to Prescribe, Supply and Administer (Approval No. 2016/AP305)

- MS: spasms not managed by conventional medicine
- Medical practitioners... acting on the written recommendation... of a Neurologist may prescribe Sativex
- The prescriber is required to state **multiple sclerosis & Neurologist name** on the prescription form.



Definitions of cannabis-based products are available on the Ministry of Health website.

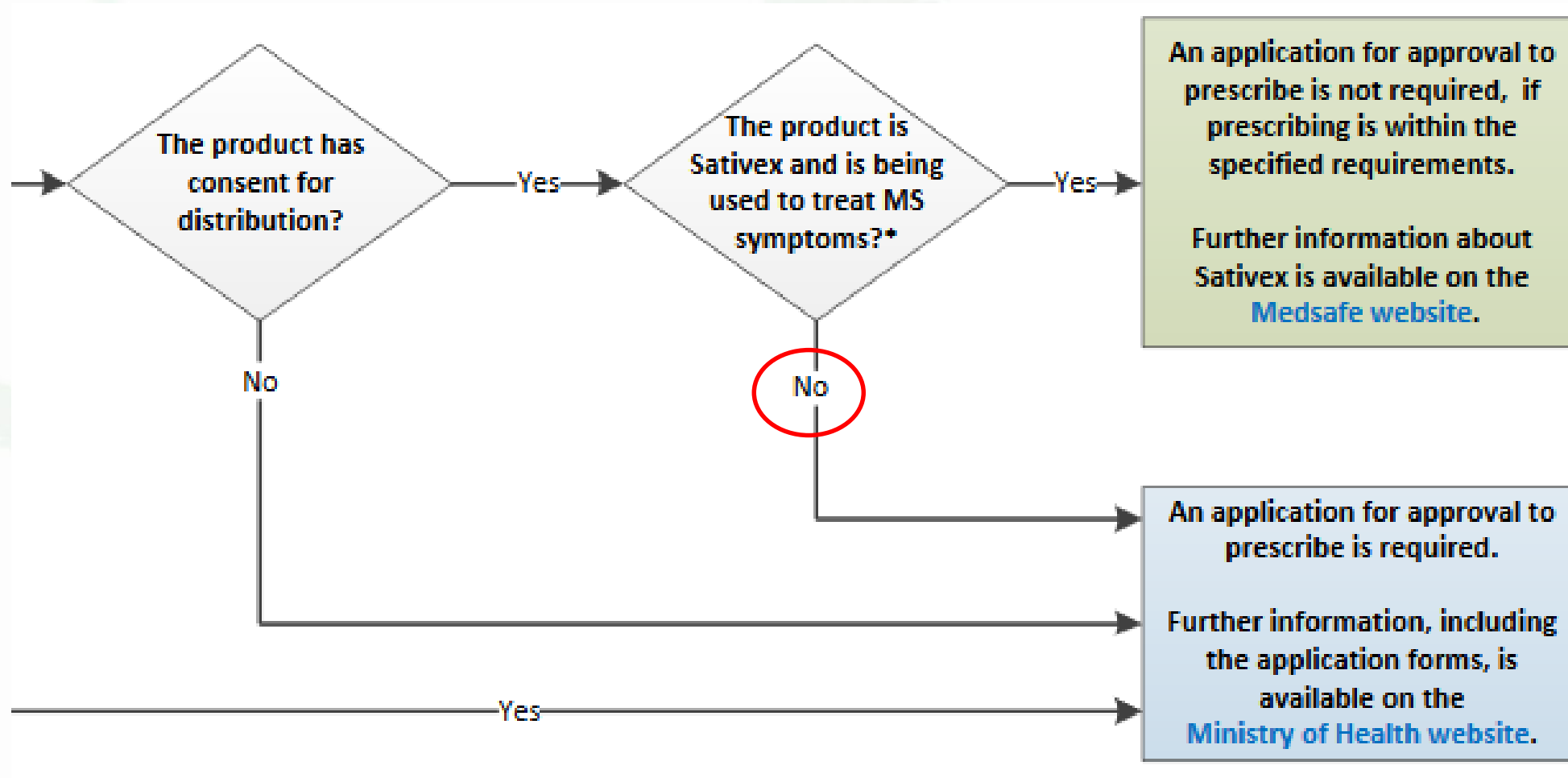
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Email Medicines Control
medicinescontrol@moh.govt.nz



3. Sativex 'unapproved use'

- Sativex application form 2 pages
- GP & Specialist signatures
- Process time 2 days (was 1 – 4 weeks).
- SPECIAL AUTHORITY FORM – My proposal for an efficient approval system!!!
- However, as GPs we know **personalised vs evidence based medicine**, we work in 'zones of therapeutic uncertainty'
Please don't restrict the clinical indications for use of medicinal cannabis.

Application for APPROVAL TO PRESCRIBE SATIVEX FOR AN UNAPPROVED USE

A completed and signed copy of this form must be submitted for each application for use of Sativex for each specified patient.

Please note that Sativex® is currently not funded by PHARMAC.

1. PATIENT DETAILS

Full name of patient:	
Full Street address:	
Date of Birth:	
NHI Number:	
Is this a Renewal of an existing approval	

2. INDICATION FOR PROPOSED USE OF SATIVEX

3. PATIENT INFORMED CONSENT

The patient should be advised of the benefits and risks associated with treatment with Sativex. The patient should be advised that its use is on a trial basis and if reassessment indicates no benefit (or significant risks) then treatment may be stopped.

"I, the patient named above, am willing to use Sativex®. I have been informed, and understand, the benefits and risks associated with its use."

4. APPLICANT DETAILS (Sativex will only be dispensed for prescriptions written by the applicant)

The applicant must be a General Practitioner (GP) or specialist who normally provides medical care to the patient.

Full name:	
NZ Medical Council Number:	
Full practice Address	
Phone:	
Email:	

5. SPECIALIST ENDORSEMENT

Specialist assessment and endorsement of the proposal to use Sativex, must be issued by a practitioner who is registered with the New Zealand Medical Council as being competent in the scope of practice appropriate to the management of the condition to be treated.

Full name:	
NZ Medical Council Number:	
Full practice Address	
Phone:	
Email:	

6. ENDORSEMENT AND CONFIRMATION

Signature of patient's prescriber (applicant)

Date

Signature of endorsing specialist

Date

Sativex dosing

<https://medsafe.govt.nz/profs/Datasheet/s/sativexspray.pdf>

Titration period:

A titration period is required to reach optimal dose. The number and timing of sprays will vary between patients.

The number of sprays should be increased each day following the pattern given in the table below. The afternoon/evening dose should be taken at any time between 4 pm and bedtime.

When the morning dose is introduced, it should be taken at any time between waking and midday.

The patient may continue to gradually increase the dose by one spray per day, up to a maximum of 12 sprays per day, until they achieve optimum symptom relief. There should be at least a 15 minute gap between sprays.

Day	Number of sprays in the morning	Number of sprays in the evening	(Total number of sprays per day)
1	0	1	1
2	0	1	1
3	0	2	2
4	0	2	2
5	1	2	3
6	1	3	4
7	1	4	5
8	2	4	6
9	2	5	7
10	3	5	8
11	3	6	9
12	4	6	10
13	4	7	11
14	5	7	12

Sativex Adverse Effects

See New Zealand Data Sheet for full list

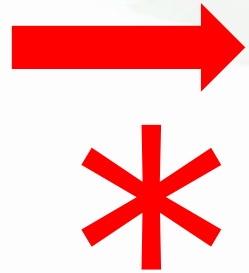
- Very common $\geq 10\%$: dizziness & fatigue during titration
- Common: 1 – 10%: appetite changes, depression, disorientation, dissociation, euphoria, asthenia, feeling drunk, malaise, blurred vision, vertigo, constipation, diarrhoea, dry mouth, mouth ulcers, nausea, vomiting

Sativex Drug-Drug Interactions (DDIs)

- Unlikely with usual doses of Sativex
- Cytochrome P450 metabolism,
- CYP3A4 inhibitors may increase THC levels
 - Ketoconazole, itraconazole, ritonavir, clarithromycin
- CYP3A4 inducers may reduce THC levels
 - Rifampicin, carbamazepine, phenytoin, St Johns Wort
- Care with sedatives, alcohol
- Anti-spasticity agents may increase risk of falls.

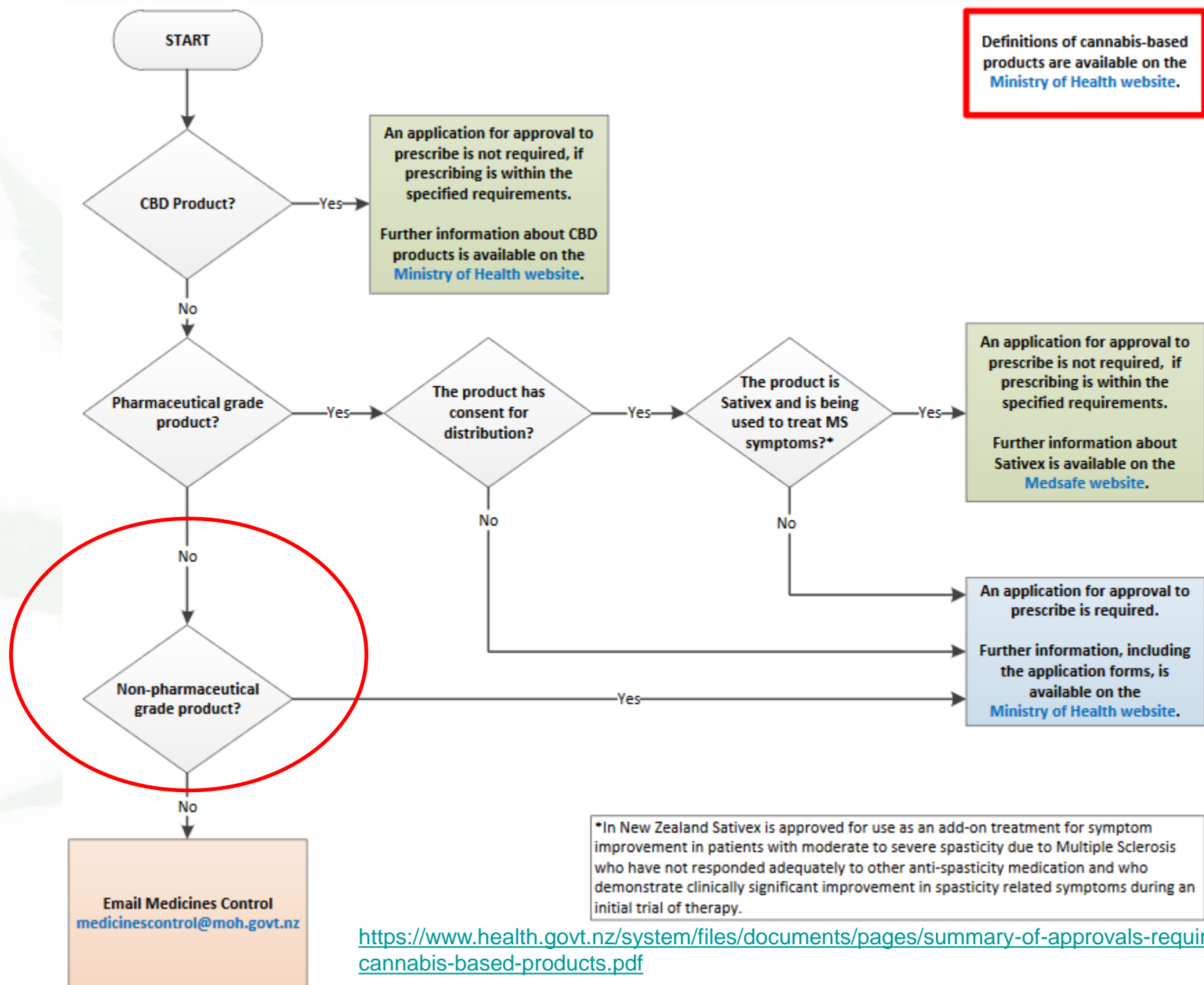
4. Application for Ministerial approval to prescribe a pharmaceutical grade cannabis-based product without consent for distribution in New Zealand under Regulation 22 of the Misuse of Drugs Regulations 1977

Specialist
only



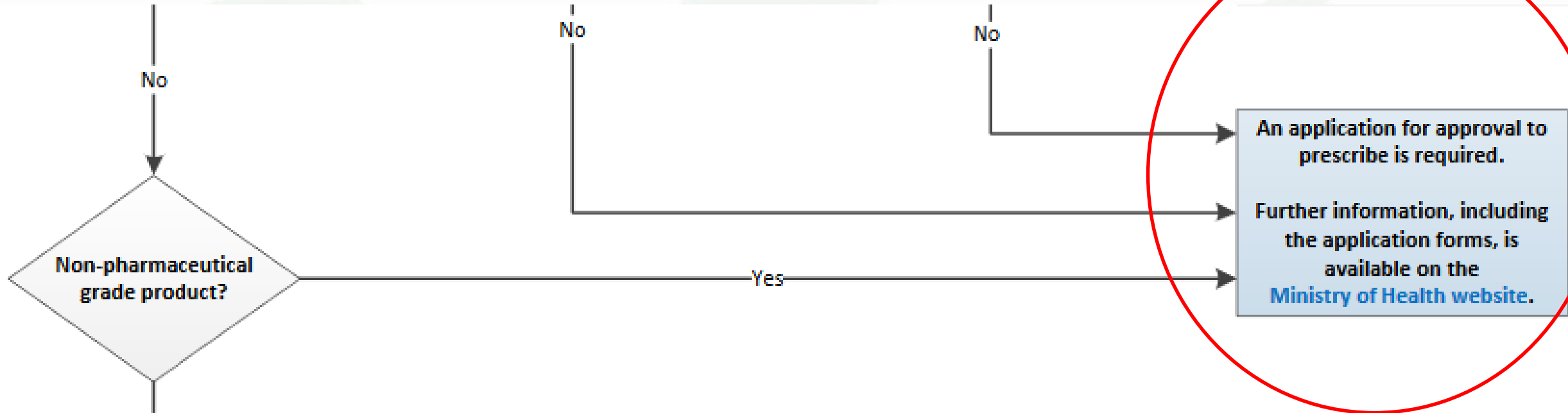
Please note that the Government does not support the use of unprocessed or partially processed cannabis leaf or flower preparations for medicinal use.

<http://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/prescribing-cannabis-based-products>



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

*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.



5. Non-pharmaceutical grade cannabis-based products

- <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis/prescribing-cannabis-based-products#3>

**5. MoH
guidelines
for
> 2% THC**

**Application for Ministerial approval to prescribe a
non-pharmaceutical grade cannabis-based product
under Regulation 22 of the Misuse of Drugs
Regulations 1977**

A completed and signed copy of this form must be submitted for each application for Ministerial approval to prescribe a non-pharmaceutical grade cannabis-based product for a specified patient.

IMPORTANT INFORMATION FOR APPLICANTS
Applications to prescribe non-pharmaceutical grade cannabis-based products are considered by the on a case by case basis. Please review the guidelines used for assessing applications listed on the Medicines Control section of the Ministry of Health website.

1. PRODUCT

Name of the product:

Do you have a Certificate of Analysis?

- No
- Yes – please attach details



Please attach any evidence of potential benefits of the use in the product in the condition(s) to be treated and known adverse effects. |

5. Non-pharmaceutical grade cannabis-based products

- The following matters are taken into account when assessing applications for Ministerial approval to prescribe non-pharmaceutical grade cannabis-based products regulated by Regulation 22 of the Misuse of Drugs Regulations 1977:
 - a. severe or life-threatening condition
 - b. evidence that reasonably applicable conventional treatments have been trialled and the symptoms are still poorly controlled
 - c. evidence that the risk/ benefit of the product has been adequately considered by qualified clinical specialists – that is, the risk of treatment with an unproven product is less than the risk of non-treatment and account has been taken of any evidence of potential benefit and weighed against known adverse effects
 - d. application from a specialist appropriate to the medical condition being treated or the Chief Medical Officer of a District Health Board
 - e. applicant or specialist prescriber has sought adequate peer review eg, Hospital Ethics Committee approval, Drug or Therapeutics Committee review, review by other specialists in the condition being treated and/or specialist colleagues involved in the treatment of the patient
 - f. provision of a Certificate of Analysis, preferably from an accredited laboratory, so that the concentration of the active ingredient(s) is known
 - g. patient or guardian has provided informed consent.

6. Compassionate Cannabis

- Medical Cannabis Awareness NZ,
<http://mcawarenessnz.org/>
- Questions about prescribing medicinal cannabis
can be emailed to

medicinescontrol@moh.govt.nz

<https://bpac.org.nz/2018/docs/cannabinoids.pdf>

Misuse of Drugs (Medicinal Cannabis) Amendment Bill – 17 December 2018

- Introduce an exception and a statutory defence for terminally ill people to **possess and use illicit cannabis** and to possess a cannabis utensil

(1B) In this Act, a person requires palliation if, in the opinion of a medical practitioner or nurse practitioner, the person has an advanced progressive life-limiting condition and is nearing the end of their life.

MEDICAL CERTIFICATE

Re: Certification of need for palliation under the Misuse of Drugs (Medicinal Cannabis) Amendment Act 2017.

I the undersigned certify that:

I examined [Patients name] of [address] on [date].

[Patients name] has an advanced progressive life-limiting condition and is nearing the end of their life.

[Patients name] requires palliation to ease their symptoms.

Example template for the Certification of need for palliation under the Misuse of Drugs (Medicinal Cannabis) Amendment Act 2017

Date

To Whom It May Concern,

Re: Certification of need for palliation under the Misuse of Drugs (Medicinal Cannabis) Amendment Act 2017.

I the undersigned certify that:

I examined [Patients name] of [address] on [date].

[Patients name] **has an advanced progressive life-limiting condition and is nearing the end of their life.**

[Patients name] requires palliation to ease their symptoms.

Name and designation of medical practitioner / nurse practitioner

Medical Council / Nursing Council Number

Those amendments—

- allow a medical practitioner, a person who holds a licence to operate a pharmacy under the [Medicines Act 1981](#), or a person who holds a licence to deal in controlled drugs under the Act to import a CBD product without a licence to import the product and to possess and supply that CBD product:
- allow CBD products to be supplied, administered, or prescribed **without** the approval of the Minister of Health:

Patient requests to import CBD

‘...if it is addressed to you, ensure it is appropriately labelled, less than three months' supply and accompanied by a prescription or letter from a New Zealand registered doctor that exactly matches the quantity, strength, and form of the imported medicine and shows the doctor is aware they are being imported. The prescription should be included inside the package, along with a certificate of analysis for the product or sufficient labelling to confirm it meets the definition of a prescription only CBD product.’

(MoH Advisor email to patient 5/2/19)



Vaporisers: The Hemp Store

www.hempstore.co.nz

Vaporite digital desktop



Herb chamber

mouthpiece

Focus handheld



Arizer Air handheld



Acknowledgements

- Presenters at the United in Compassion Australian Medicinal Cannabis Course & Symposium, Melbourne June 2017
- Assoc Prof David Caldicott
- Prof Nick Lintzeris
- Dr Jeffrey Hergenrather
- Dr Viola Brugnattelli
- Justin Sinclair
- Dr Teresa Towpik

Any Questions?

~NGA MIHI NUI~

Thank you.

Please note that I take questions and referrals

Video consultations available

www.cannabiscare.nz

doctor@cannabiscare.nz