Chair
Cabinet Business Committee

Medicinal cannabis: 100-Day Action

Proposal

1. This paper seeks Cabinet policy approval for legislative changes that will deliver our commitment to improve access to medicinal cannabis for people with a terminal illness or chronic pain.

Executive summary

2. The government has a 100-day commitment to introduce legislation to enable access to medicinal cannabis for people with a terminal illness or chronic pain. This commitment is guided by the principles of fairness, quality and safety, and compassion.

3. Based on these principles, I propose a Misuse of Drugs Amendment Bill that will:

    i) introduce **an exception and a statutory defence** for terminally ill people to possess and use illicit cannabis

    ii) introduce a **medicinal cannabis scheme** that enables access to products made to a quality standard in a timely way, and

    iii) **deschedule cannabidiol** as a controlled drug.

4. As a compassionate measure, I propose providing **an exception and a statutory defence** for the possession and use of illicit cannabis for terminally ill people who are reasonably expected to die within 12 months. It is well known that some people who are close to the end of their life are using illicit cannabis to relieve their symptoms. While there are potential health and safety risks for people consuming illicit cannabis, I believe that the circumstances of people with a terminal illness are different. This proposal is intended as an interim measure for terminally ill people until affordable product made to a quality standard is delivered via the medicinal cannabis scheme.

5. At the same time, I am committed to delivering a policy approach that enables people, including those with terminal illness or chronic pain, to access medicinal cannabis products made to a quality standard and prescribed through their medical practitioner. I want these products to be affordable and readily available. To enable this I propose a **medicinal cannabis scheme** with the following components:

    - a medicinal cannabis advisory committee to review the current prescribing requirements

- domestic cultivation and manufacture of cannabis products to a quality standard, and
- the ability to set minimum quality standards for both domestically manufactured and imported product to improve patient safety and give medical practitioners confidence about the available products.

6. A government agency will be required to oversee the delivery of the Scheme and meet our UN Drug Convention obligations. I will return to Cabinet in March 2018 with further details of the regulatory framework and ongoing funding requirements. This timing will enable relevant considerations for Budget 2018.

7. I also propose to investigate appropriate mechanisms by which the Government could choose to support people who are unable to afford cannabis products made to a quality standard. Any proposals for government assistance will require careful consideration to ensure PHARMAC's funding model is not compromised.

8. **Cannabidiol** (CBD) is a substance found in cannabis that has potential therapeutic value and little or no psychoactive properties. In February this year the Expert Advisory Committee on Drugs (the Committee who provides expert advice to the Minister of Health on drug classification issues) reviewed the classification of CBD. The Committee advised that CBD has potential therapeutic value and little or no psychoactive properties and should be descheduled as a controlled drug.

Background

'Medicinal Cannabis' has different meanings

9. For medical practitioners, medicinal cannabis might refer to an approved pharmaceutical product, such as Sativex (made by GW Pharmaceuticals). At the other end of the spectrum, members of the general public might think of it as plant material that people have grown themselves.

10. In this paper **illicit cannabis** means cannabis that has been grown, processed (ranging from dried leaf material through to oils and balms), and supplied illegally. Product made to a **quality standard** means there is reasonable certainty the composition is true-to-label and contaminants (such as pesticides and heavy metals) are minimised. Products that are **consented** are assessed and approved by Medsafe. Consented products have clinical trial data and meet quality manufacturing standards.

There is emerging but incomplete evidence for the medicinal use of cannabis

11. A 2017 review of the evidence by an expert US committee concluded there was substantial evidence that cannabis or cannabinoids are effective for relieving chronic pain, reducing multiple sclerosis spasticity, and relieving nausea and vomiting due to chemotherapy.

12. The Committee found initiating recreational cannabis use at a younger age increases the likelihood of developing problem cannabis use. It also found

substantial evidence of statistical association between recreational cannabis use and the development of schizophrenia and other psychoses, with the highest risk among the most frequent users.

13. The appropriate place for cannabis products in patient treatment plans is yet to be defined for many conditions. Research studies suggest that specific cannabis formulations may be useful for some patients. However, there is a lack of evidence to demonstrate that cannabis products are more effective than conventional treatments.

Current access to cannabis products under prescription in New Zealand

14. Medsafe is the New Zealand regulator of medicines and medical devices. Its role is to ensure medicines meet acceptable standards of safety, quality and efficacy. Products that meet these standards are 'consented' and can be advertised in New Zealand. The Medsafe process provides information to medical practitioners about a product's efficacy, side effects, the recommended dosage, and other details that enable a sound and defensible prescribing decision to be made.

15. Products that are 'non-consented' can still be prescribed by medical practitioners, but the medical practitioner must assure themselves that the product meets reasonable quality standards and that there is a clinical basis for prescribing.

16. The Misuse of Drugs Act 1975 (the Act), and the Medicines Act 1981, allows access to consented and non-consented cannabis products via prescription from a medical practitioner. Prescribing by a specialist is required for non-consented cannabis, specialist oversight of GP prescribing is required for Sativex. The medical practitioner makes a clinical judgement about the benefit and risk of a particular cannabis product for a particular patient.

17. Under the Misuse of Drugs Regulations 1977 (the Regulations), pre-approval from the Minister of Health (delegated to Ministry of Health) to prescribe, use and administer cannabis is required for the majority of prescriptions. This pathway does not restrict access by patient group but it does generally require the product prescribed to either be consented or meet a sufficient quality standard.

18. Since December 2016, GPs with specialist oversight have been able to prescribe Sativex for its consented use (as an add-on treatment in Multiple Sclerosis) without approval from the Ministry.

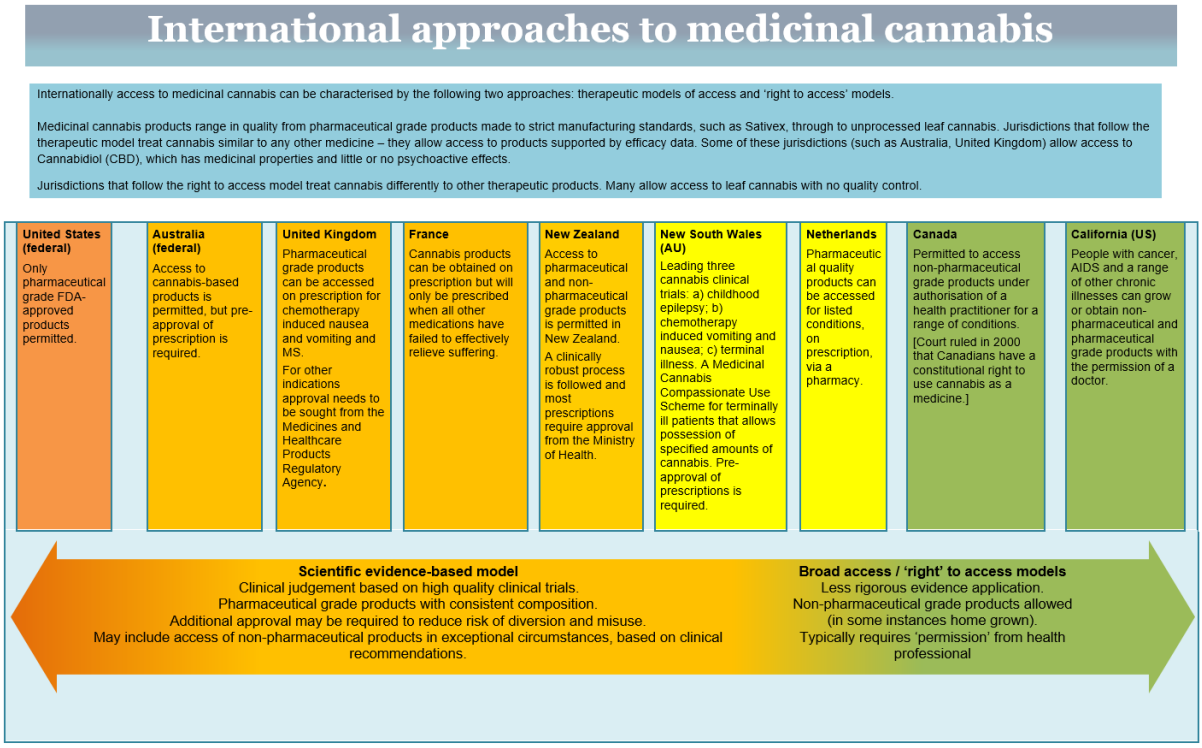
19. Since 2008, a total of 255 applications to prescribe cannabis products have been approved (as at 1 November 2017). The majority of these (243 applications or 95%) have been for Sativex. This reflects the fact that Sativex is available and consented in New Zealand whereas other cannabis products have to be imported under licence and most are not consented anywhere.

20. In September this year, changes to the Regulations came into effect to facilitate access to cannabidiol (CBD) products with up to two percent other cannabinoids (including Δ9-tetrahydrocannabinol (THC)). These changes removed the requirement for pre-approval to prescribe, the requirement for an import licence and some storage and record keeping requirements. While there are no CBD

products made to a quality standard currently in New Zealand, the Ministry of Health has been advised that there will likely be product available by the end of this year.

Different countries and jurisdictions have different approaches

21. The table below sets out a comparison of approaches across eight countries. Similar to New Zealand, countries such as Australia, the United Kingdom and the Netherlands allow access to a product made to a specified standard through a medical practitioner on prescription. Further detail is provided in appendix one.



22. New Zealand is a signatory to the United Nations Single Convention on Narcotic Drugs 1961. The Single Convention acknowledges the need to have a pathway for patients to access controlled drugs as medicines but requires jurisdictions to have controls around access and availability.

Consideration

Despite a legal pathway, access to affordable medicinal cannabis products remains problematic

23. Barriers for people to access include:

- **A reluctance to prescribe**: the medical model instils a sense of caution towards new products where evidence of efficacy is limited and side-effects uncertain, over established products with known efficacy and clinical knowledge of side-effects. It is also likely that the process to obtain pre-approval to prescribe, source a product (made to a quality standard with the desired composition), and arrange import, are further barriers for medical practitioners.

- **Accessing suitable products**: there are a limited range of products available that are made to quality standards and strict controls around the import and export of cannabis products internationally. Sativex is the only Medsafe consented product, as such it is able to be advertised, and is available on prescription through a pharmacy. Any other cannabis products are currently non-consented and therefore cannot be advertised.
- **Cost**: Sativex costs $1100 to $1400 per month, depending on dose. No cannabis product is subsidised by PHARMAC. Some medical prescribers have identified an alternative overseas product, gone through the application process and arranged licences to import, only to find that the cost of the product is almost equivalent to Sativex and unaffordable for the patient.

24. The PHARMAC funding model relies on managing all pharmaceutical funding within a fixed budget so that decisions are fair and there is national consistency around availability of products. In 2015 PHARMAC's Pharmacology and Therapeutics Advisory Committee considered funding Sativex for multiple sclerosis, pain and epilepsy. The Committee recommended funding be declined due to weak or no available evidence but will continue to review the evidence and may change its advice in the future.

25. As the quality of manufacture is generally reflected in the cost of cannabis, illicit cannabis can be significantly cheaper than products made to a quality standard. Some people obtain cannabis from illicit sources and experiment with self-medication, without the supervision of a medical professional. People may be unaware of the possibility of contamination and variability of composition within products that are not made to quality standards.

Proposal

26. The Government has a 100-day commitment to introduce legislation to improve access to medical cannabis. This commitment is guided by the following principles:

Fairness
All people with a similar health need who would benefit from accessing cannabis products can do so, in a timely way, not just those that can afford it.

Quality and safety
The government has a responsibility to ensure that access to products has appropriate oversight so that harm is minimised.

Compassion
Health and safety considerations may be different for people in their last days of life.

27. Based on these principles, I propose a Misuse of Drugs Amendment Bill that will:

    i) introduce **an exception and a statutory defence** for terminally ill patients to possess and use illicit cannabis,

    ii) introduce a **medicinal cannabis scheme** that enables access to products made to a quality standard in a timely way, and

    iii) **deschedule cannabidiol** as a controlled drug.

i) Provide an exception and a statutory defence for possession and use of illicit cannabis product for terminally ill people

28. I propose providing **an exception** and **a statutory defence** for possession and use of illicit cannabis for people with a terminal illness, on compassionate grounds.

29. While there is a legal pathway to access cannabis products it is well known that some people who are close to the end of their life are using illicit cannabis to relieve their symptoms. My intent is to take a compassionate approach for this particular group of people where the usual concerns around product safety, quality and long-term risks are different.

30. The proposed legislation will:

- provide that a person who possesses or uses Class B or Class C cannabis products, including cannabis oil and plant material, does not commit an offence if the person has a certificate from a medical practitioner certifying that the person has a terminal illness, and
- provide a defence against prosecution for use and possession of Class B or C cannabis products, including cannabis oil and plant material, where the person is unable to produce immediate evidence of a terminal illness at the time of questioning by Police, but able to produce evidence in court.

31. In doing so I expect to be able to give security and confidence to terminally ill people so that they do not need to fear criminal convictions. I recommend that this is an interim measure until readily available and more affordable product is able to be accessed via the proposed medicinal cannabis scheme.

32. I am aware that there are different definitions of terminal illness. I propose the exception and statutory defence provisions are for people of any age who are reasonably expected to die within 12 months.

The exception and statutory defence provisions will not apply to chronic pain

33. I do not propose extending the exception and statutory defence to people in chronic pain. Chronic pain is difficult to define, subjective, and would potentially cover a large patient group (21 percent of adult New Zealanders experience chronic pain). Extending this proposal to this group would be likely to result in significant legal dispute around the definition of chronic pain.

34. In addition, most people with chronic pain are likely to have many years of life before them, and it is appropriate that they receive medical advice about use of cannabis products, including potential interaction with other medication and medical conditions. People with chronic pain could be prescribed a cannabis product under the current legal pathway if their medical practitioner supported its use for that individual.

Enforcement considerations

35. The exception means that a terminally ill person who has a medical certificate does not commit an offence if they possess or use cannabis, and if they show their medical certificate to police on request they will avoid being charged and prosecuted for the personal possession and use of cannabis. The statutory defence is effectively a backstop for a terminally ill person who is not able to provide immediate evidence of their illness at the time of questioning, but can produce evidence in court.

The exception and statutory defence provisions do not provide a supply route for terminally ill

36. This proposal does not provide a defence for terminally ill people to import or cultivate cannabis nor does it provide a defence for those who supply cannabis to terminally ill people. An exception and/or statutory defence for family/whanau and friends who access illicit cannabis on behalf of a terminally ill person would be for supply, which carries significantly higher penalties than for possession and use. I do not propose an exception or statutory defence for this group.

37. It is recommended that the exception and the statutory defence provisions for terminally ill people are reviewed in 2020. The development of a legitimate supply chain via the proposed medicinal cannabis scheme (as outlined below) would remove the need for people to obtain illicit cannabis for medicinal purposes.

ii) Introduce a medicinal cannabis scheme

38. A key barrier for people wanting to access medicinal cannabis is the lack of available products other than Sativex, made to a quality standard, and the resulting time and cost required to locate and import products.

39. I intend addressing this barrier by establishing a **medicinal cannabis scheme** (the Scheme) that will enable timely access to cannabis products made to a quality standard. Appendix two compares the current process to access cannabis with the process under the proposed scheme.

40. A government agency will be set up to oversee the delivery of the Scheme, in accordance with our obligations under the United Nations (U.N.) Single Convention on Narcotic Drugs 1961 (the Single Convention). I expect the agency will be established as a business unit within the Ministry of Health, similar to the Psychoactive Substances Regulatory Authority.

41. The agency would develop a regulatory framework to enable local cultivation and manufacture, set quality standards for domestic and imported products and provide product information for prescribers. The agency would also oversee the import of cannabis produced overseas. This approach acknowledges the current obstacles of importing overseas product and would be similar to the Australian initiative to establish a domestic supply of cannabis. I intend to seek Cabinet approval for a regulatory framework in March 2018.

42. The Scheme has the following components:

    a) a medicinal cannabis advisory committee
    b) domestic cultivation and manufacture of cannabis
    c) minimum quality standards for all cannabis products.

a) Medicinal cannabis advisory committee

43. I intend convening a **medicinal cannabis advisory committee** in early 2018 that brings together experts, consumers and others. This will be a valuable mechanism to engage with health practitioners about cannabis to gain a fuller understanding of any concerns, information needs and process issues. The first task for the Committee will be to review the current prescribing process (ie, the need for pre-approval to prescribe). The Committee will be time limited until the agency is established. The need for an advisory committee post-establishment of the agenda will be considered as part of the implementation work.

b) Domestic cultivation and manufacture of cannabis

44. I propose enabling **domestic cultivation and manufacture** of medicinal cannabis products to a quality standard. This will increase the range of products available.

45. Establishing domestic cultivation and manufacture will take time. Australia has taken 24 months to establish their domestic scheme and are yet to provide product to patients.

c) Setting minimum quality standards for all cannabis products

46. I propose enabling the **setting of minimum quality standards** that products supplied and manufactured under licences must meet. These standards would apply to both imported products and those manufactured in New Zealand.

47. The requirement that all products meet these standards will give medical practitioners assurance that the cannabis products available for supply in New Zealand meet those minimum standards.

iii) Deschedule cannabidiol as a controlled drug

48. Cannabidiol (CBD) is a substance found in cannabis that has potential therapeutic value and little or no psychoactive properties. It is currently a Class B1 controlled drug.

49. In February this year the Expert Advisory Committee on Drugs (the Committee who advises the Minister of Health on drug classification issues), advised that it would be reasonable to remove CBD from the Act so it is a prescription medicine only.

50. Recognising that naturally-derived CBD products from the cannabis plant are very likely to contain small amounts of other cannabinoids, particularly THC, the Committee recommended an allowance of two percent or less of other naturally occurring cannabinoids in a CBD product.

51. Descheduling CBD requires a bill to amend the Act. In response to the Committee's advice, the previous Government removed a number of controlled drug requirements for CBD products with up to two percent other cannabinoids via regulations. The intent was to deschedule CBD with up to two percent of cannabinoids usually found in cannabis from the Act when an amendment bill was next introduced.

52. I propose utilising the proposed Misuse of Drugs Amendment Bill to deschedule CBD and CBD products with up to two percent other cannabinoids from the Act so that they are prescription medicines only. This amendment will bring New Zealand's scheduling of CBD into line with other countries, such as Australia.

Fairness and affordability

53. I am conscious that initiatives to improve access to cannabis products made to a quality standard need to be implemented in a fair way. I intend to achieve this by first taking steps to enable access to a greater number of products in New Zealand which is expected to result in cannabis products becoming more affordable. Secondly, I will investigate mechanisms by which the government could choose to support people who are unable to afford cannabis products made to a quality standard. Any proposals will require careful consideration to ensure PHARMAC's funding model is not compromised.

54. There is a lack of accurate information about the demand for cannabis products from terminally ill people. For example, we know that approximately 9000 people die from cancer each year but we do not know how many people who are terminally ill would want to use cannabis products.

55. The cost of cannabis products varies considerably as do the dosage levels required for different patients and conditions. For comparision, Sativex costs around $1200 per month. Bedrocan (the supplier of medicinal cannabis for the Netherlands), produces a range of standardised leaf products, costing between $120 and $420 per month, depending on dose.

56. I expect the agency (refer to paragraph 40) will have a role in assessing potential demand for cannabis products and could provide advice to government on the potential cost of subsidising product. Prices of product are likely to vary depending on market demand and availability.

Next Steps

57. Subject to Cabinet's approval, a draft Bill will be prepared for LEG to enable it to be introduced to Parliament within the Government's first 100 days.

58. Other than enabling the setting of standards, establishing a domestic supply (including an agency) can be achieved through new regulations. I will report back to Cabinet in March 2018 seeking agreement on the regulatory framework. This will include more detailed costings and a Regulatory Impact Analysis.

59. Ministry of Health officials will also continue to work with interested parties (medical practitioners, overseas manufacturers and domestic wholesalers) to import cannabis products made to a sufficient standard.

Consultation

60. We have consulted with the following agencies: DPMC (Policy Advisory Group), PCO, NZ Police, Ministry of Justice, Customs, ACC, Te Puni Kōkiri, Treasury, Ministry of Pacific Peoples, Oranga Tamariki and PHARMAC.

Financial implications

61. Under my proposal to establish a Scheme, establishing an agency will have start-up and ongoing operational costs. Indicative estimates of these costs are [redacted] per annum for the first four years (2018/19 to 2021/22).

62. I will report back to Cabinet in March 2018 with further detail on the proposed Scheme, including start-up and ongoing costs of an agency. This will inform Ministers' considerations as part of Budget 2018.

Human rights

63. The proposals are consistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993. A final assessment as to whether the proposed amendments are consistent with these Acts will be undertaken by the Ministry of Justice once the legislation has been drafted but before a Bill is introduced.

Legislative implications

64. This paper seeks Cabinet approval to amend the Misuse of Drugs Act 1975.

Regulatory impact analysis

65. The proposal for an exception and a statutory defence for possession and use of illicit cannabis by terminally ill people will have some regulatory impacts in terms of Police practice and Court resources (ie, if a terminally ill person defends the charge rather than pleading guilty). The LEG paper will include a Regulatory Impact Analysis.

66. The proposed Scheme and establishment of an agency to meet our obligations under the UN drug conventions will have financial implications. The March Cabinet paper will include detailed costings and a Regulatory Impact Analysis.

Gender implications

67. There are no gender implications associated with these proposals.

Disability implications

68. The intent of the proposed medicinal access scheme is to improve access to medicinal cannabis products for patients with significant conditions (for example multiple sclerosis), who do not respond to conventional treatments, as and when the products are available.

Publicity

69. The requirements around access to cannabis products are complex. It is important that information about access to cannabis is clearly communicated, realistic expectations are set, and timeframes for achieving domestic cultivation and supply are achievable. I will put out a media release supported by more information on the Ministry of Health website.

70. If the proposal for an exception and a statutory defence is supported, the Ministry will need to work with other agencies and health practitioners to develop guidelines for terminally ill people, clinicians and enforcement agencies.

Recommendations

71. It is recommended that Cabinet:

    71.1. **Agree** that the principles of fairness, quality and safety, and compassion will guide the Government's commitment to improve access to medicinal cannabis.

    71.2. **Agree** to introduce legislation that provides an exception and a statutory defence for terminally ill patients to possess and use illicit cannabis on compassionate grounds, acknowledging that the usual concerns around product safety, quality and long-term risks are different for this group.

    71.3. **Agree** in principle to introduce a medicinal cannabis scheme that enables commercial cultivation and manufacture of medicinal products made to a quality standard in a timely way, including the establishment of an agency to meet our obligations under the UN Single Convention on Narcotic Drugs 1961.

    71.4. **Agree** that the Minister of Health establish a medicinal cannabis advisory committee in early 2018 to review the current prescribing process.

    71.5. **Note** that in February 2017, the Expert Advisory Committee on Drugs advised that, based on their assessment of CBD's risk profile, lack of

psychoactive properties, and potential therapeutic value, it would be reasonable to remove cannabidiol (CBD) from the Act so it is a prescription medicine only.

71.6. **Authorise** the Minister of Health to issue drafting instructions to Parliamentary Counsel to amend the Misuse of Drugs Act 1975 to:

71.6.1. Provide an exception to the offence of possession and use of cannabis for a terminally ill person who has a medical certificate evidencing their terminal illness.

71.6.2. Provide a statutory defence against a charge of possession or use of cannabis for someone who has been diagnosed with a terminal illness.

71.6.3. Enable the setting of quality standards for products manufactured and supplied under the medicinal cannabis scheme.

71.6.4. Deschedule CBD and CBD products with up to two percent other cannabinoids from the Act so that they are prescription medicines only.

71.7. **Note** that a draft Bill will be prepared for LEG to enable it to be introduced to Parliament within the Government's first 100 days.

71.8. **Invite** the Minister of Health to report to Cabinet in March 2018 seeking agreement on the medicinal cannabis scheme's regulatory framework.

71.9. **Note** that the March 2018 Cabinet paper will seek agreement for expenses to be managed against the operating and capital spending set out in the government's Fiscal Plan and reflected in the Half-Year Economic and Fiscal Update.

71.10. **Note** that funding requirements identified in the March 2018 Cabinet paper will be sought as part of Budget 2018.

Authorised for Lodgement

Hon. Dr David Clark
Minister of Health

Appendix one

1. Different jurisdictions have a range of approaches to medicinal cannabis, but they broadly fall into two categories: the therapeutic and right to access models. The therapeutic model of access treats cannabis the same as other medicines. The right to access model broadens access to cannabis products, due to social demand rather than clinical efficacy.

Table 1. Examples of access to medicinal cannabis internationally

Jurisdiction	Overview of requirements	Supply	Who can access?
New Zealand (current)	Cannabis products can be prescribed by a doctor with pre-approval from the Ministry. Some cannabis products can be prescribed directly by a doctor, without Ministry approval. These are: • Cannabidiol (CBD), containing up to two percent of other cannabinoids • Sativex to treat spasticity associated with Multiple Sclerosis.[1]	Products can be imported with a licence issued under the Misuse of Drugs Act 1975. CBD products are exempted from the import licence requirements. Products are expensive, and other than Sativex, difficult and slow to source and import. One Tilray product is stocked onshore. The Ministry expects more in the coming months.	Doctors can prescribe CBD without the need for Ministry approval. Doctors can prescribe Sativex for people with Multiple Sclerosis without Ministry approval. Prescribing Sativex for any other condition requires a specialist recommendation and Ministry approval. Other cannabis products can be accessed with Ministry approval via a specialist prescription. Only medical practitioners can prescribe unapproved products. The conditions for which cannabis is prescribed is at the discretion of the medical practitioner.
New Zealand (proposed)	Terminally ill patients will have an exception and statutory defence for possession and use of illicit cannabis, or can access product via prescription.	A domestic cultivation scheme is proposed, which will produce cannabis products to a quality standard that can be accessed via prescription. Australia took 24 months to set up a domestic scheme. They do not have product available yet. The exception and statutory defence provisions for the terminally ill do not provide for supply.	Cannabis can be accessed via prescription from a doctor. Terminally ill will have a defence for possession and use without a prescription. Verification of terminal illness by a doctor will be required for the defence.

1 Ministry of Health, Prescribing cannabis-based products, accessed at http://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/prescribing-cannabis-based-products.

Jurisdiction	Overview of requirements	Supply	Who can access?
Australia	Medicinal cannabis is available under the Authorised Prescriber Scheme (APS) and Special Access Scheme (SAS), and can be accessed through clinical trials. Some states also require State-level approval.[2] APS allows a doctor, who has been approved by the Therapeutic Goods Association (TGA), to prescribe cannabis to a specified group of patients.[3] SAS allows the import or supply of medicinal cannabis for a single patient on a case by case basis. Sativex is not funded.	A regulatory framework for cultivation has been established.[4] Local product is not expected to be available until next year. An Authorised Prescriber can import medicinal cannabis, or approval to import can be sought by a medical practitioner through the SAS scheme. An import permit from the Office of Drug Control is required to import product. Unapproved medicinal cannabis cannot be imported by individuals.	The conditions for which cannabis is prescribed is at the discretion of the doctor. Under SAS, patients who are terminally ill do not require TGA approval, but TGA approval is required in all other cases.
Canada	Individuals with approval from their health care provider can access medicinal cannabis. A Bill to legalise recreational cannabis access will be considered in 2018.[5]	Patients can either register with a licenced producer, who will send cannabis directly to them; or grow cannabis themselves, or designate someone else to grow it for them.[6]	A doctor must specify that a patient has a qualifying condition. These conditions may include: nausea and vomiting associated with chemotherapy; symptoms (pain, insomnia and depression) experienced by cancer and AIDS patients; pain and muscle spasms associated with multiple sclerosis; and palliative care.[7]
United States (Federal)	Possession of cannabis is illegal, except when used in approved research settings.[8] Cannabis is considered to have no therapeutic use.	Federal law prohibits the import, export, or cultivation of cannabis. This prohibition includes moving cannabis that has been legally obtained between states.[9] The Food and Drug Administration (FDA) has approved synthetic cannabis products	Federal law prohibits possession and use of cannabis.

2 Australian Government, Department of Health, Therapeutic Goods Administration, Access to medicinal cannabis products, accessed at https://www.tga.gov.au/access-medicinal-cannabis-products.

3 Australian Government, Department of Health, Therapeutic Goods Administration, Authorised prescribers, accessed at https://www.tga.gov.au/form/authorised-prescribers.

4 Australian Government, Office of Drug Control, Medicinal cannabis cultivation and production licences and permits, accessed at https://www.odc.gov.au/medicinal-cannabis-cultivation-and-production-licences-and-permits.

5 Government of Canada, Status of Cannabis Laws in Canada, accessed at https://www.canada.ca/content/dam/hc-sc/documents/services/campaigns/27-16-1808-Factsheet-The-Facts-eng-03.pdf

6 Government of Canada, Fact Sheet: Access to Cannabis for Medical Purposes Regulations, accessed at https://www.canada.ca/en/health-canada/news/2016/08/fact-sheet-access-to-cannabis-for-medical-purposes-regulations.html

7 Government of Canada, Consumer Information – Cannabis (Marijuana, marijuana), accessed at https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-use-marijuana/licensed-producers/consumer-information-cannabis-marihuana-marijuana.html

8 U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, "Title 21 United States Code (USC) Controlled Substances Act - section 812. Schedules of controlled substances", https://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm

9 California Medical Association, "Physician Recommendation of Medical Cannabis", http://www.mbc.ca.gov/Licensees/Prescribing/medical_marijuana_cma-recommend.pdf

Jurisdiction	Overview of requirements	Supply	Who can access?
		Marinol and Syndros, which are cannabinoid-based medications used to induce appetite in AIDS patients, and to treat nausea and vomiting associated with chemotherapy.[10]	
California	Medicinal cannabis has been legal since Proposition 215 passed in 1996, which allowed access for patients with a doctor's recommendation.[11] Medical use will be regulated under the Medical and Adult-Use Cannabis Regulation and Safety Act, expected to be ready in 2018. This will permit and regulate for-profit cultivation, distribution, manufacturing, testing, dispensary, and transportation.[12] Recreational use is permitted under Proposition 64, introduced in 2016.[13] Adults over 21 can legally use, possess, and share cannabis, and grow it at home.	A patient may cultivate up to six mature plants or 12 immature plants, and have up to eight ounces of dried cannabis.[14] For recreational use, people are allowed up to one ounce of dry cannabis, eight grams of concentrated cannabis, or six live plants.	Patients are required to have written documentation by physician of diagnosis of serious medical condition and that medicinal cannabis is appropriate.[15] Serious medical condition includes: AIDS, anorexia, arthritis, cachexia, cancer, chronic pain, glaucoma, migraine, persistent muscle spasms (e.g. multiple sclerosis), seizures (e.g. epilepsy), and severe nausea.[16]

10 U.S. Food and Drug Administration, FDA and Marijuana: Questions and Answers, https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#notapproved

11 Bureau of Cannabis Control California, About us, accessed at http://bcc.ca.gov/about_us/

12 California Legislative Information, SB-94 Cannabis: medicinal and adult use, accessed at https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB94

13 Bureau of Cannabis Control California, About us, accessed at http://bcc.ca.gov/about_us/

14 ibid

15 ibid

16 California Medical Association, Physician Recommendation of Medicinal Cannabis, Guidelines of the Council of Scientific Affairs Subcommittee on Medical Marijuana Practice Advisory, accessed at http://www.mbc.ca.gov/Licensees/Prescribing/medical_marijuana_cma-recommend.pdf

Jurisdiction	Overview of requirements	Supply	Who can access?
Colorado	Medicinal cannabis use has been legal in Colorado since Amendment 20 was passed in 2000, which allowed use for approved patients with written medical consent.[17]	Patients can possess up to two ounces of medical cannabis, and may cultivate no more than six cannabis plants. [18]	Physicians are not able to prescribe due to federal legislation, but may provide a written recommendation that the patient has a debilitating condition and might benefit from the use of medical marijuana. Recommendations may be written for these conditions: cancer; glaucoma; HIV or AIDS; and post-traumatic stress disorder; or any of these symptoms: cachexia; persistent muscle spasms; seizures; severe nausea; and severe pain.
Netherlands	The Netherlands allows access to Bedrocan products from a doctor. The Netherlands have set up a centralised Office of Medicinal Cannabis which takes possession of all of the cannabis produced in line with the U.N. Conventions.[19]	Bedrocan, a medicinal cannabis company based in the Netherlands, is the sole supplier of medicinal cannabis. Bedrocan granulated plant products are made to a good manufacturing practice (GMP) standard, and are administered by an inhaler. The cannabis is supplied to the Office of Medicinal Cannabis who then supplies it to pharmacies.[20] Prescriptions are then dispensed by pharmacies, similar to any other medicine.	The Office of Medicinal Cannabis lists conditions (such as pain and muscle spasms or cramps, chronic neuropathic pain, and nausea) for which cannabis is recommended, but a doctor may prescribe cannabis at their own discretion.[21]
Israel	Israel has a government agency for cannabis, the Israel Medicinal Cannabis Agency (IMCA), within the Ministry of Health.[22] Israel has a medicalisation model, under which the IMCA has developed quality assurance standards for all components of the supply chain (cultivation, manufacture, distribution, and	Israel are moving to bring cannabis as close to a medicine as possible. Cultivation and sale from traditional cultivators is to cease. Standardised product is to be dispensed by pharmacies. Aiming to have a medical grade cannabis by the end of this year.	Israel has a list of conditions for which medicinal cannabis can be prescribed in the following fields of medicine –oncology, gastroenterology, pain, infectious diseases, neurology, palliative care and psychiatry. A licence to use is issued after standard

17 McMaster Health Forum (2017), Rapid Synthesis: Examining the Impact of Decriminalizing or Legalising Cannabis for Recreational Use, accessed at https://www.mcmasterforum.org/docs/default-source/product-documents/rapid-responses/examining-the-impact-of-decriminalizing-or-legalizing-cannabis-for-recreational-use.pdf?sfvrsn=8

18 ibid

19 Netherlands Cannabis Bureau, The Office of Medicinal Cannabis, accessed at https://www.cannabisbureau.nl/english

20 ibid

21 Ministry of Health, Welfare, and Sport, Medicinal Cannabis Information for Patients, accessed at https://www.cannabisbureau.nl/Media/Default/PDF/5089-A5-BMC-Pat-ENG-web_35842.pdf

22 State of Israel Ministry of Health, Medicinal Cannabis Unit, accessed at https://www.health.gov.il/English/MinistryUnits/HealthDivision/cannabis/Pages/default.aspx

Jurisdiction	Overview of requirements	Supply	Who can access?
	security). They have also developed clinical guidelines known as the "Green Book".		treatments have been exhausted for listed indications with these fields.
Germany	Medical use is permitted under legislation which came into effect March 2017. This mandates that German's public health insurance system covers the cost of cannabis medicines prescribed by doctors.[23] Individuals are not prosecuted for possession of up to five grams for recreational use, with regional variability. Germany have set up an agency to supply medicinal cannabis (in line with the UN Conventions). They have completed a tender procurement process and have a number of suppliers including Bedrocan and Tilray. Cannabis will be able to be prescribed by a GP in Germany and is not restricted to specified conditions.	Germany will create a state-regulated program in 2019 to cultivate cannabis for medicinal use. A cannabis agency will be created within the Federal Opium Agency to oversee cultivation. The agency will contract farms to grow cannabis, oversee each stage to ensure product produced is pharmaceutical grade.[24] Pharmacists will dispense cannabis, either as cannabis extract in capsules, or liquid form, or as dried flower buds. Until the cultivation programme is up and running, cannabis will be imported. Grow your own is not allowed.	Doctors can prescribe cannabis based medicines to treat pain, nausea from chemotherapy, and other chronic ailments. Cannabis can only be prescribed as a last resort if patients cannot be treated in any other way, and only in very limited cases.
Ireland	Ireland's controlled drug system is similar to New Zealand. Cannabis, and any products extracted that are psychoactive, are controlled under the Misuse of Drugs legislation. Medicinal use is currently only permitted with Minister approval.[25] Sativex is consented, but not funded. CBD products are legal.	A licence issued by the Minister is currently required to import cannabis. [27] Ireland have set up an agency to supply medicinal cannabis (in line with the UN Conventions).	Currently, the Minister of Health must grant a licence under the Misuse of Drugs Act where a proposed course of cannabis has been endorsed by a consultant. Medicinal cannabis can only be prescribed for certain indications and must be prescribed by a specialist. Ireland are looking to set up an access programme[28], which is likely to be for patients

23 The Commonwealth Fund, New German Law on Medicinal Use of Cannabis, accessed at http://www.commonwealthfund.org/publications/newsletters/international-health-news-briefing/2017/march-april-2017/germany/new-german-law-on-medical-use-of-cannabis

24 British Medical Journal (2017), Germany sets up new agency to oversee production of medicinal cannabis, accessed at http://www.bmj.com/content/356/bmj.j70

25 Irish Statute Book, S.I No. 69/1998 – Misuse of Drugs (Designation) Order, 1998, accessed at http://www.irishstatutebook.ie/eli/1998/si/69/made/en/print

27 ibid

28 Ireland Department of Health, Statement on Medicinal Cannabis Bill, accessed at http://health.gov.ie/blog/press-release/statement-on-medicinal-cannabis-bill/

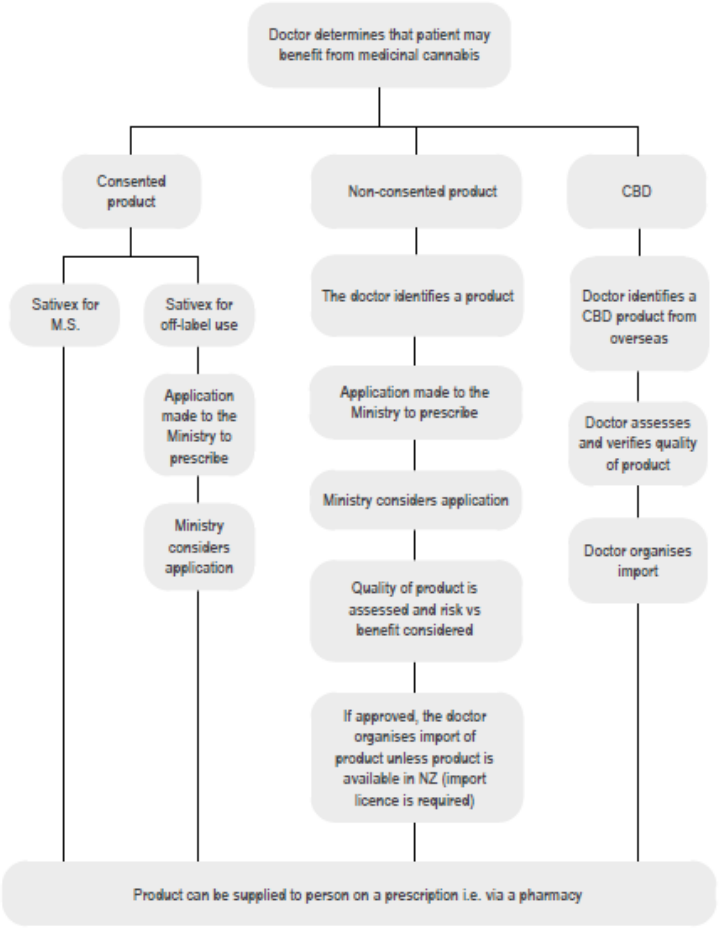
Jurisdiction	Overview of requirements	Supply	Who can access?
	A Bill to legalise medicinal cannabis has been rejected by the Health Committee in July 2017, because the Bill proposed to decriminalise cannabis not just for medical purposes.[26] Ireland are currently looking to see where they can get supply from and are deciding if they will reimburse for medicinal cannabis. Their intention is to no longer require Ministerial approval for specialists to prescribe medicinal cannabis. Ireland has developed and published quality standards.		(who do not respond to conventional treatments) with: • Severe, refractory epilepsy. • Spasticity associated with multiple sclerosis. • Intractable nausea and vomiting associated with chemotherapy

26 Houses of the Oireachtas, Joint Committee on Health, Report on Scrutiny of the Cannabis for Medicinal Use Regulation Bill 2016, July 2017, accessed at http://www.oireachtas.ie/parliament/media/committees/health/Report-on-Scrutiny-of-the-Cannabis-for-Medicinal-Use-Regulation-Bill-2016-[PMB].pdf

Appendix two

Access to medicinal cannabis

Now



Interim steps

1. Medicinal cannabis advisory committee will review the prescribing process, including whether to retain the pre-approval requirement.

2. Domestic cultivation and supply established to address stock shortages. This will require establishing an agency.

Proposed scheme

Under the scheme, the Agency:

- Regulates domestic cultivation, manufacture, and imports
- Sets quality standards for domestic and imported product
- Provides guidance to prescribers