

Medicinal Cannabis Scheme

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Consultation

The Government has committed to establishing a Medicinal Cannabis Scheme (the Scheme) to improve access to quality medicinal cannabis products through:

- enabling the commercial cultivation of medicinal cannabis and the manufacture of medicinal cannabis products in New Zealand
- setting standards for medicinal cannabis products so that medical practitioners can prescribe them with more confidence.

A regulatory system, with controls on the cultivation of cannabis and the manufacture and supply of medicinal cannabis products, is needed to support the Scheme. The regulations are being developed to establish the regulatory system.

The purpose of this consultation document

This consultation paper sets out the details of the Medicinal Cannabis Scheme and the regulatory proposals needed to support the Scheme. It provides an opportunity for the Ministry of Health to seek feedback from the public, industry, health care professionals and other interested stakeholders on the proposals, with a particular focus on:

- (a) the proposed requirements for domestic cultivation of cannabis for medicinal purposes and manufacture of medicinal cannabis products
- (b) the proposed quality standards that may apply to processes and to medicinal cannabis products
- (c) prescribing requirements, including information that will be available to prescribers on medicinal cannabis products
- (d) proposed requirements after the medicinal cannabis product goes to market.

This feedback will help shape the regulatory proposals needed to support the Medicinal Cannabis Scheme.

Layout of the consultation paper

This consultation paper is divided into eight main sections.

- **Part A: Context and overview of the Medicinal Cannabis Scheme** – describes the context, objectives and background to the Scheme, gives a high-level overview of its supporting framework, and discusses Te Tiriti o Waitangi and equity under the Scheme.
- **Part B: Proposed quality standards** – details the proposed quality standards for medicinal cannabis products to ensure they are produced to minimum standards of quality.
- **Part C: Licensing of products** – provides an overview of the proposed licensing regime, including the conditions that must be met to be issued a licence.

- **Part D: Distribution of products** – details how medicinal cannabis products are distributed.
- **Part E: Proposed prescribing requirements and providing information to prescribers** – outlines proposals for the prescribing requirements for medicinal cannabis products and points to information available to assist medical practitioners.
- **Parts F: Controls for products on the market and proposed licence fees** – proposes how products will be monitored after they are allowed on the market and the actions that manufacturers and suppliers will have to take.
- **Part G: proposed licence fees** – set out the proposed fees that would apply to licences issued under the Scheme.
- **Part H** – lists proposals and consultation questions by audience.

How to provide feedback

You can provide feedback by:

- using our online tool at <https://consult.health.govt.nz/medsafe/medicinal-cannabis-scheme-consultation>. This is our preferred way to get feedback.
Note, you can complete your submission over a number of sessions and save it as you go. If you select 'Save and come back later', you will be sent an email with a unique link that will let you return to edit and submit your response. This link can be shared with your colleagues if you require their contribution to, or review of, the submission. Once you have completed your submission, you will be sent a pdf copy for your records, **or**
- sending an electronic submission to medicinal_cannabis@health.govt.nz using our downloadable Microsoft Word template from the Ministry of Health website at <https://www.health.govt.nz/publication/medicinal-cannabis-scheme-consultation>. If you have any issues with the template, please email us at medicinal_cannabis@health.govt.nz

The closing date for submissions is Wednesday 7 August at 5pm.

Your feedback is important because it will help shape the final proposals, ensuring they are workable and that the purpose of the legislation is achieved. We appreciate you taking the time to make a submission.

We have added questions throughout the document and summarised the proposals and questions in the table in Part H, which also notes and colour codes the main audience for each section. For example, much of *Part E: Prescribing* has questions for prescribers, though some of these may also be of interest to consumers, industry, or other groups. We encourage you to answer or provide comments on any proposals or questions you feel are relevant.

Note that your submission may be requested under the Official Information Act 1982. If this happens, the Ministry of Health will normally release your submission to the person who asks for it. If you consider there are good reasons to withhold it, please clearly indicate these in your submission. See Part H for more information.

Next steps after the consultation

The Ministry of Health will analyse the feedback and consult with the Medicinal Cannabis Advisory Group (see Appendix 3) before providing advice to the Government on the outcomes of the consultation, including any proposed changes. The Ministry of Health will then seek approval from Cabinet on the regulatory proposals and work with the Parliamentary Counsel Office to draft the proposed Misuse of Drugs (Medicinal Cannabis) Regulations.

We are aiming to have the above regulations made by 18 December 2019 and to have the Medicinal Cannabis Scheme operational in the first quarter of 2020.

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Executive summary

There has been increasing interest in the therapeutic properties of medicinal cannabis for a range of health conditions. Currently, medicinal cannabis products are available on prescription with ministerial approval. However, there is a lack of affordable products made to a quality standard available in New Zealand.

The process of determining the quality of a medicinal cannabis product and then sourcing and supplying it to a patient takes time, and because there are no products being manufactured in New Zealand, all products must be imported. This can be a burden on prescribers and a barrier to prescribing. This has led to some New Zealand patients accessing cannabis illegally for medicinal use, with issues around the quality of products, continuity of supply, consistency of cannabinoid content, possibility of prosecution and unregulated high prices.¹ All of these issues create risks to patients.

The Medicinal Cannabis Scheme is being established to increase access to medicinal cannabis products, including increasing supply by making it possible for these products to be made in New Zealand and requiring products to meet quality standards, so medical practitioners (doctors) and nurse practitioners can prescribe with confidence.

The Scheme proposes to increase supply of products through licensing the cultivating of cannabis in New Zealand and the manufacture and supply of medicinal cannabis products made to quality standards. For the Scheme to meet these objectives, it must deliver quality, affordable products to patients and be commercially sustainable.

The Scheme covers cannabis products originating from the cannabis plant for medicinal use. It does not cover medicinal cannabis products manufactured from synthetic cannabinoids or cultivating and manufacturing cannabis products for non-medical use.

This consultation document sets out the key aspects and the regulatory proposals needed to establish a Medicinal Cannabis Scheme. Proposals cover:

- setting quality standards for cultivation, manufacturing and finished products
- licensing, distribution (including imports and exports) and prescribing
- monitoring and controls on products, including collection and sharing of information
- fees and charges.

In addition, there are many questions that aim to inform the shape of the Medicinal Cannabis Scheme. All proposals and questions relating to the Scheme can be found throughout this document and summarised in *Part H: Proposals and consultation questions*. Where questions are more relevant for a particular audience or audiences, this is noted in the text – for example, questions for medical practitioners (doctors) and nurse practitioners about prescribing medicinal cannabis products.

¹ Forty-two percent of New Zealand cannabis users reported medicinal use in the previous 12 months, with users aged 55+ years reporting higher rates of medicinal use. www.health.govt.nz/publication/cannabis-use-2012-13-new-zealand-health-survey

Part A: Scheme background, objectives and scope

A1: Background

1. There has been increasing interest in the therapeutic properties of medicinal cannabis treatments for a range of health conditions. Currently, medicinal cannabis products are available on prescription. However, there is a lack of affordable products made to a quality standard available in New Zealand.
2. The process of determining the quality of a medicinal cannabis product and then sourcing and supplying it to a patient takes time. Currently all products must be imported. This can be a burden on prescribers, and a barrier to prescribing.
3. This has led to some patients accessing cannabis illegally, with concerns about poor quality of products, continuity of supply to meet therapeutic needs, unknown consistency of cannabinoid content, fear of prosecution, and unregulated prices. This increases risks to patients.
4. In December 2017 the Government made a commitment to improve access to affordable, quality medicinal cannabis products. Cabinet agreed, in principle, to introduce a medicinal cannabis scheme that would enable the commercial cultivation of cannabis for medicinal purposes, and the manufacture of medicinal cannabis products made to a quality standard.
5. The Misuse of Drugs (Medicinal Cannabis) Amendment Bill was introduced into Parliament in December 2017 and came into effect on 18 December 2018.²
 - People requiring palliation are eligible for an exception and statutory defence for possession of cannabis and cannabis utensils.³
 - Cannabidiol (CBD) and CBD products containing up to 2 percent of other cannabinoids that are specified substances are no longer controlled drugs under the Misuse of Drugs Act 1975 (but they remain as medicines regulated under the Medicines Act).

² The cultivation, production, manufacture, import, export, supply and use of cannabis and cannabis-derived products are strictly regulated in New Zealand through several other laws, which include Misuse of Drugs Act 1975; Medicines Act 1981; Customs and Excise Act 2018; Biosecurity Act 1993; Agricultural Compounds and Veterinary Medicines Act 1997; and Food Regulations 2015.

³ In the Misuse of Drugs (Medicinal Cannabis) Amendment Act 2018: 'a person requires palliation if, in the opinion of a medical practitioner or a nurse practitioner, the person has an advanced progressive life limiting condition and is nearing the end of their life'.

- Regulations can be made to prescribe standards for all stages of cultivation, production and manufacture, and for medicinal cannabis products.
 - A licence holder under the Medicinal Cannabis Scheme can use local varieties of cannabis for cultivation.
 - Regulations on the quality standards must be made no later than 18 December 2019.
6. This consultation is part of the work led by the Ministry of Health to prepare for the establishing of the Medicinal Cannabis Agency and the operational implementation of the Medicinal Cannabis Scheme in the first quarter of 2020.

A2: Overview of medicinal cannabis

7. The term medicinal cannabis can mean different things, depending on the context it is used in. However, in this document a medicinal cannabis product means a medicine that can generally only be prescribed by a medical practitioner, who will judge its suitability for the patient.⁴ A medical practitioner, as used in this document, means all doctors registered by the Medical Council of New Zealand, including general practitioners and any other speciality.
8. The cannabis plant is made up of many chemical components, which vary in strength and effect depending on the genetic origin of the plant and how it is grown, prepared and consumed. Many of the components found in the plant, known as cannabinoids, are thought to have medicinal properties and vary in strength and effect. More than 100 cannabinoids have been identified, including tetrahydrocannabinol (THC) and CBD.
9. It is important to note that while cannabinoids may produce beneficial effects, they also have risks. For those interested in more information, the National Academies of Sciences, Engineering, and Medicine provided a comprehensive report in 2017.⁵ In addition, the World Health Organization (WHO) reviewed cannabis and cannabis-related substances at the 40th Expert Committee on Drug Dependence in 2018.⁶

⁴ The exception to this is CBD products that have approval or provisional approval from the Ministry of Health to be advertised or sold. Once there are approved CBD products, these will be able to be prescribed by nurse practitioners.

⁵ Media release on The Health Effects of Cannabis and Cannabinoids report www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=24625&_ga=1.220514077.426798793.1484265042; and Report: The Health Effects of Cannabis and Cannabinoids www.nap.edu/catalog/24625/the-health-effects-of-cannabis-and-cannabinoids-the-current-state

⁶ www.who.int/medicines/access/controlled-substances/ecdd_40_meeting/en/ A 2018 WHO report found naturally occurring CBD is safe and well tolerated in humans (and animals), is not associated with any negative public health effects and does not have the potential for addiction or abuse. However, cannabis, and specifically the cannabinoid THC, poses risks to individuals, including potential for regular users to develop dependence.

10. As medicinal cannabis products are prescription medicines, the medical practitioner (doctor) is best placed to advise patients on the risks and benefits of their use. The Ministry of Health will provide medical practitioners with information on the use of medicinal cannabis. Note that there is already helpful information created by other countries, including Australia and Canada.⁷

A3: How medicinal cannabis products are currently approved and prescribed

11. Understanding how medicinal cannabis products are currently approved and prescribed in New Zealand is key to understanding this document.

Approval of medicinal cannabis products

12. Approval is officially called 'consent', but to make things simpler we use the more common terms 'approved' and 'unapproved' medicinal cannabis products throughout the document, and refer to this approval being by the Ministry of Health. In terms of approval, medicinal cannabis products fall into three groups:
 - approved medicines
 - provisionally approved medicines
 - unapproved medicines.
13. For a medicine to be approved it needs to have supporting data to demonstrate safety, effectiveness and quality. This approval allows the medicine to be advertised to medical practitioners (doctors) and sold. This approval is from the Minister of Health. However, in practice, this approval is delegated to the Ministry of Health.
14. Currently the only approved medicinal cannabis product is Sativex.TM
15. Provisionally approved medicines are broadly the same as approved medicines. However, the Ministry of Health approval is only for up to two years, with restrictions on the conditions the medicines can be prescribed for, for who and/or for how long. There are currently no medicinal cannabis products that have provisional approval.
16. Unapproved medicines cannot be advertised and they can only be supplied on prescription for named patients. Unapproved medicines can be that way for many reasons. Some may have a strong history of effective medical use overseas but have not been approved here as there has not been a demand, while others may have less trial data or be experimental.

⁷ www.canada.ca/en/health-canada/services/drugs-medication/cannabis/information-medical-practitioners/information-health-care-professionals-cannabis-cannabinoids.html and www.tga.gov.au/medicinal-cannabis-guidance-documents

Prescribing of medicinal cannabis products

17. Currently for medicinal cannabis products, except for CBD products, additional approval from a specialist working within a relevant scope of practice is required.⁸ For example, approval from a paediatrician or neurologist may be needed for medicinal cannabis products to treat complex epilepsy in a child.
18. All medicinal cannabis products except for CBD products are controlled drugs, which are more tightly controlled.
19. Approval to prescribe medicinal cannabis products (except CBD products) is also needed from the Ministry of Health.⁹
20. CBD products only require a prescription from a medical practitioner and do not require additional approvals.

A4: Objective and scope of the Medicinal Cannabis Scheme

21. The objective of the Scheme is to improve patient access to quality, affordable medicinal cannabis products. To achieve this, the Scheme needs to enable the cultivation and manufacture of medicinal cannabis products in New Zealand, and the ongoing importing of overseas products to encourage competition and improve affordability of quality products.
22. The Scheme also needs to provide medical practitioners (doctors) and nurse practitioners with confidence about the range of quality medicinal cannabis products available. The key regulatory challenges in achieving this objective are to ensure products meet appropriate quality standards, to keep compliance costs at an acceptable level and to minimise the risk of medicinal cannabis being diverted into the illicit market.
23. The Scheme must recognise the principles of Te Tiriti o Waitangi (the Treaty of Waitangi) and support equitable health outcomes while supporting consumer access to, and individual responsibility for, their medical care. The design and implementation of the Scheme should also enable equity of access to the economic benefits of a medicinal cannabis industry while supporting New Zealand's trade and economic objectives.

⁸ There are 36 areas of medicine, or scopes of practice, within which you can be registered and work as a specialist in New Zealand, including as a general practitioner. The list is available online: www.mcnz.org.nz/registration/scopes-of-practice/vocational-and-provisional-vocational/types-of-vocational-scope

⁹ Note that ministerial approval has been granted to enable the prescribing of Sativex™ as an add-on treatment for symptom improvement in patients with moderate or severe spasticity due to multiple sclerosis without the requirement to make an application for approval to prescribe.

24. Te Tiriti o Waitangi means the Crown has a duty to protect and promote the health of Māori. This includes a responsibility to respond to Māori health aspirations and meet Māori health need. Figure 1 shows the interrelationship between these two responsibilities.¹⁰
25. Responding to Māori health aspirations is a Te Tiriti o Waitangi obligation and includes achieving equity for Māori. Within a Te Tiriti o Waitangi framework, delivering on the rights and needs of Māori is essential, given that Māori have the poorest overall health status and are significantly disadvantaged in terms of health outcomes.

Figure 1: Supporting Māori health aspirations and equitable health outcomes



26. The Crown recognises that its obligation to Māori goes beyond just remedying disadvantage and reducing inequities; it involves enabling Māori to flourish as Māori, and lead their own aspirations for health, wellbeing and prosperity.
27. The Ministry of Health has made explicit its commitment to honouring the Crown's special relationship with Māori under Te Tiriti o Waitangi. The Ministry's *Statement of Strategic Intentions*¹¹ outlines the Ministry's undertaking to actively meet its Te Tiriti o Waitangi obligations, including reducing health disparities for Māori.

Scope of the Scheme

28. The Scheme will only cover medicinal cannabis products originating from the cannabis plant. It will not cover medicinal cannabis products manufactured from synthetic cannabinoids (synthetic pharmaceuticals that mimic the effect of cannabinoids on the body).

¹⁰ The diagram was developed by the Health Quality & Safety Commission.

¹¹ Ministry of Health. 2017. *Statement of Strategic Intentions 2017–2021*. Wellington: Ministry of Health.

29. The Scheme distinguishes between regulated pharmaceutical products used for medicinal purposes and using cannabis for recreational purposes. The cultivation of cannabis for recreational use is not part of the scheme and medicinal cannabis products will only be available as prescription medicines, prescribed by a medical practitioner (doctor).

A4: Questions for all:

Please provide any overall comments on the proposals in the consultation document.

Do you think the current proposals and options in this document would meet the Government's objective of improving patient access to quality, affordable medicinal cannabis products? Please explain why/why not.

Equity

30. It is a priority for the Government to deliver equitable health outcomes for all New Zealanders. The Ministry of Health has adopted the following definition of equity for use across the health and disability system:
- In Aotearoa New Zealand, people have differences in health that are not only avoidable but unfair and unjust. Equity recognises different people with different levels of advantage require different approaches and resources to get equitable health outcomes.
31. Inequities in medication access and usage, health outcomes, disease or health risks between ethnic groups have been extensively documented in Aotearoa New Zealand and internationally.
32. While barriers to access are broader than the cost of medicines, the lack of affordable medicinal cannabis products means cost is currently a significant barrier. Regulation of pharmaceuticals and public funding of pharmaceuticals in New Zealand are two separate processes. To be considered for national public funding, suppliers of medicinal cannabis products subject to the proposed regulations would also need to separately apply to PHARMAC for public subsidy and be prioritised for national funding as per PHARMAC's usual processes.
33. The design and implementation of the Medicinal Cannabis Scheme must support equitable health outcomes and not inadvertently create any barriers to access. The Medicinal Cannabis Scheme should allow for future models of care and service delivery that would facilitate more equitable access, particularly in community-based settings.
34. As part of this, the Ministry of Health needs to work to ensure that people understand what the Scheme means for them. Building on the engagement done to support the public consultation, the medicinal cannabis regulations finalised in December 2019 will be supported by targeted communications and engagement during the first half of 2020. This will involve engaging with industry, the medical community, consumers and other key stakeholders, including organisations with a key role in meeting Māori health needs.

35. Another key area in supporting greater equity is monitoring and evaluation. As detailed in Part F, there will be ongoing monitoring and regular evaluation of the Medicinal Cannabis Scheme to assess progress against its objectives, as well as identifying any barriers to access, gaps in understanding and other issues. This will also include specific engagement with organisations with a focus on Māori health needs.
36. There should also be equity of access to the economic benefits of a medicinal cannabis industry. It is important that the Medicinal Cannabis Agency has the capacity and capability to support iwi and other Māori groups to understand the medicinal cannabis requirements for industry.
37. In addition, there are a number of business support services available to individuals and groups who are interested in entering the industry, including the following.
 - Te Arawhiti the Office for Māori Crown Relations is a new Crown agency dedicated to fostering strong, ongoing and effective relationships with Māori across government.
 - Māori Business Growth Support is about helping Māori establish and grow their business by providing information and advice and brokering relationships.
www.tpk.govt.nz/en/whakamahia/maori-business-growth-support

A4: Question for all:

What do you think is the best way to achieve equity of access to the economic benefits of a medicinal cannabis industry?

A4: Question for patients / consumers:

Have you (or someone you know) had difficulty in accessing medicinal cannabis products (eg, due to cost, availability of products, patient–prescriber relationship, information on products available)? If yes, please provide comments as to why.

A4: Questions for prescribers:

As a prescriber, what do you see as the barriers to patient access to medicinal cannabis products?

Please indicate your position on the following statement:

‘There are greater barriers to accessing medicinal cannabis products for particular patients.’ If you agree, please discuss the barriers.

Meeting our international obligations

38. The Government also has responsibility for ensuring that any scheme for the cultivation of cannabis for medicinal purposes is consistent with New Zealand’s international obligations under three international drug control conventions:
 - the Single Convention on Narcotic Drugs 1961 (the Single Convention)
 - the Convention on Psychotropic Substances 1971
 - the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988.

39. The purpose of the Single Convention is to establish a framework to prevent abuse and diversion of controlled narcotics (strong prescription medicines for pain relief), while supporting the availability of such drugs for medicinal purposes.
40. Under the Single Convention, New Zealand has an obligation to establish an agency to control the commercial production and supply of cannabis for medical use, and to report to the International Narcotics Control Board (responsible for the implementation of the conventions) on volumes of production and manufacture.

A5: Medicinal Cannabis Agency

41. The Medicinal Cannabis Agency will be established within the Ministry of Health, as it is the most effective and efficient mechanism to enable the Scheme.
42. This is because the Ministry of Health already licenses controlled drugs used for a therapeutic purpose, other therapeutic products and other uses of cannabis (for example, industrial hemp, and the cultivation of low-THC hemp seeds for food). The Ministry can use existing knowledge and expertise, and ensure requirements across therapeutic products and controlled drugs are clear and consistent.
43. The functions of the Medicinal Cannabis Agency will include (but are not limited to):
 - overseeing the licensing of growers, processors, manufacturers, importers, exporters and wholesale distributors of medicinal cannabis products
 - monitoring compliance with licence conditions, including the requirement for medicinal cannabis products to meet quality standards
 - monitoring unapproved medicinal cannabis products for adverse effects on patients
 - collecting and reporting on data to the International Narcotics Control Board about medicinal cannabis production and use in New Zealand
 - developing or endorsing guidance for the use of medicinal cannabis products
 - monitoring the Medicinal Cannabis Scheme to assess progress in achieving its objectives.

Part B: Quality standards for medicinal cannabis products

44. The primary reason for quality standards is to protect patients. Compliance with quality standards for imported or locally manufactured medicinal cannabis products under the Medicinal Cannabis Scheme will give New Zealand medical practitioners, as well as potential consumers and export markets, confidence that the medicinal cannabis products meet minimum standards of quality.

B1: What the quality standards will cover

45. This section will discuss the quality standard requirements that can be set for some, or all, of the following.
- *Cultivation*: a cultivation standard describes procedures that should be followed to ensure that plants are grown, collected, processed and stored in a way that allows plant material with a consistent composition to be produced, and minimises the risk of contaminants (for example, pesticides, heavy metals, mould).
 - *Manufacture*: a manufacturing standard ensures that products are consistently produced.
 - *Active pharmaceutical ingredient (API)*: a standard ensures that the quality of the active ingredients (which produce the effects of the drugs) is suitable and assured to be free of contaminants before it is used in manufacturing the finished product.
 - *Final product*: a standard ensures the product:
 - composition is verified (ie, the levels of THC and CBD and other APIs) and contaminants (eg, pesticides, heavy metals, mould) are minimised
 - is fit for purpose so it behaves as expected when taken or administered (eg, if it is a tablet, the standard would measure the rate it dissolves, hardness, size, and uniformity of dosage)
 - is stable over time: the manufacturer provides evidence that the product will be stable under the recommended storage conditions over its entire shelf life
 - ingredients that are not the active ingredients of the drug are suitable and free from contaminants. These non-active ingredients are known as excipients.

B2: Proposed quality standards for cultivation

46. The starting material is generally the dried or cured flowers of the cannabis plant.
47. The purpose of cannabis cultivation is to produce the starting material used in the production of an active pharmaceutical ingredient (API) or the final medicinal cannabis product. Manufacturers may cultivate their own starting material, or purchase it from one or more licensed suppliers under contract or commercial agreement.
48. The quality of starting materials produced from cultivation activities is influenced by the:
 - botanical characteristics of the cultivars (specific plant varieties)
 - parts of the plant sourced to be used as finished product (eg, cannabis flowers)
 - cultivation practices and conditions and chemical treatments before or after harvesting (eg, pesticides and fertilisers), and environmental conditions
 - harvesting, processing, drying, moisture content and transport conditions
 - profile of the active constituents of the starting material (eg, the amount of different types of cannabinoids)
 - contamination/toxic constituents such as pesticide residues, microbial levels, mycotoxins, toxic elements (eg, heavy metals), solvent residues
 - stability of the constituents of the starting material
 - packaging materials used and storage conditions.
49. Note that cultivation will be not be required to be indoors. However it would be harder to meet the requirements for cultivation growing outdoors, including requirements for security and for the quality of the starting material.
50. There are three different options we are seeking feedback on for the quality management of the cultivation process.

A. **Manufacturers would determine the desired quality for the starting material. No quality standard would be set by the regulator for cultivation.**

Under this option, manufacturers would be responsible for determining the quality of starting materials required for the manufacture of quality APIs. This could be requiring compliance with a cultivation process standard such as Good Agricultural Practices (GAP) or setting product specifications for starting material. This has the advantage of allowing manufacturers to set starting material requirements. These requirements would reflect the extent of processing and extraction required for producing an API for manufacturing a quality medicinal cannabis product.

Under this option, cultivators who supply multiple manufacturers may need to meet different quality standards for the starting material for different manufacturers. The Medicinal Cannabis Agency would license the cultivation activity but would have no direct oversight of the quality of the starting

material. However, the manufacturer may require testing of starting materials to verify the quality required to manufacture the API to specification.

- B. **The regulator would set a cultivation process standard such as GAP**, or a similar agricultural process standard, to address the specific requirements of growing, collecting and primary processing of cannabis plants that are used for medicinal purposes.

Under this proposal, the regulator would audit the cultivator's agricultural practices. The cultivator would be responsible for documenting and conducting quality controls, processes and standard operating procedures to meet good agricultural practices. Aspects that could be considered for audit under this proposal would include:

- pesticide use
- fertilisers, growth promoters (eg, fertiliser), growth regulators and irrigation (water quality)
- growing mediums (soil or another substance through which plant roots grow and extract water and nutrients)
- harvest, drying and processing
- destruction of unneeded organic material.

- C. **The regulator would set a product quality standard for starting materials.**

It may be beneficial to test the starting material to ensure the quality of the cultivated cannabis before entering the manufacture process. The aspects of the starting material to be tested include verifying the identity of the plant, testing for the presence of and profile of the active constituents (for example, CBD, THC or other cannabinoids), and ensuring there is not contamination from pesticides, heavy metals, etc. It can also be important to prevent the mixing of plant material with active ingredients that are not derived from the plant, such as synthetic cannabinoids.

A quality standard for starting material enables early identification of critical attributes like contaminants (eg, heavy metals or pesticides). This is important as contaminants may be diluted during the manufacturing process, so are more difficult to identify if you are only testing the finished product. However, testing against a quality standard at API stage would mitigate this risk.

Under this proposal, the regulator would set the New Zealand Product Quality Standards Monograph (Appendix 2) as the quality standard for starting material.¹²

The cultivator would be responsible for ensuring that the starting material meets the quality standard, and would be required to provide evidence and documentation to prove this. The Medicinal Cannabis Agency would be responsible for reviewing the evidence to verify that the starting material meets the product quality standard. The three options above are also summarised in Table 1, so they can be more easily compared.

¹² A monograph is an article that is written to deal with various aspects of a subject, such as quality requirements and test methods for cannabis.

Table 1: Options for the quality management of the cultivation process

Options	Cultivator	Manufacturer	Medicinal Cannabis Agency (the regulator)
<p>Option A: Cultivator must meet the manufacturer’s quality requirements</p>	<p>Meets the manufacturer’s quality requirements for cultivation process or starting material – provides evidence to the manufacturer</p>	<p>Sets quality requirements for cultivation process or for starting material; checks evidence provided by the cultivator before accepting starting material</p>	<p>Licenses the cultivation activity but has no oversight of the starting material</p>
<p>Option B: Cultivator must follow cultivation process standard set by the regulator</p>	<p>The cultivator meets cultivation process standard set by the regulator</p>	<p>The manufacturer checks that the cultivator follows cultivation process standard (eg, via evidence of audits by the regulator)</p>	<p>The regulator sets the cultivation process standard (eg, New Zealand Good Agricultural Practice (GAP) guidelines or similar).¹³ The regulator would audit the cultivator’s agricultural practices against the cultivation process standard</p>
<p>Option C: Cultivator must meet the product quality standard for starting material set by the regulator</p>	<p>The cultivator tests each batch of starting material to ensure it meets the quality standard or cultivator sends each batch for testing by a licensed laboratory, and provides evidence of compliance to the regulator. The product quality standard specifies the kinds and amounts of ingredients it may contain (or not contain, such as pesticides, heavy metals)</p>	<p>The manufacturer checks that the cultivator meets the product quality standard (eg, via certificates of analysis or regulator verification)</p>	<p>The regulator sets the quality standard for the starting material, assesses evidence provided by the cultivator and verifies that each batch meets the quality standard</p>

¹³ The GAP guidelines or the WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants, or similar, cover the use, process and documentation requirements for pesticides, fertilisers, plant growth promotions/regulators, irrigation (water quality), growing mediums, harvesting, drying and processing, packaging, storage and distribution.

B2: Questions for industry and researchers

Which of the three options for the cultivation standard do you prefer?

In your view, what are the advantages and disadvantages of each of the options?

If you prefer option B (Regulator sets a cultivation process standard), which cultivation process standard(s) would be your preference?

How likely are you to apply for a licence to commercially cultivate cannabis for medicinal purposes if the preferred option is

- option A Manufacturer sets a process or a starting material product standard?
- option B Regulator sets a cultivation process standard?
- option C Regulator sets quality standard for starting material?

Do you or your organisation currently hold a licence to cultivate cannabis for medicinal or scientific research purposes?

How likely are you to apply for a licence to commercially cultivate cannabis for medicinal purposes?

B3: Proposed quality standards for manufacturing

51. Setting a quality standard for manufacturing is a critical part of ensuring that medicinal cannabis products are fit for their intended use as a medicine, and do not place patients at risk due to inadequate safety or quality.
52. There is no universally accepted standard for the manufacture of medicinal cannabis products. Internationally, many countries (including Australia, Japan and those in the European Union) have followed the medicines guidelines under Good Manufacturing Practice (GMP) for the manufacture of medicinal cannabis products. European jurisdictions that have permitted the use of medicinal cannabis have classified the product as medical and have established pharmaceutical grade controls as a requirement from the onset of medicinal cannabis legalisation. The EU-GMP¹⁴ guideline covers good manufacturing practices for all medicinal products.
53. Currently in New Zealand the quality manufacturing standard followed by all medicines manufacturers is Good Manufacturing Practice. The EU-GMP Guidelines and the New Zealand Code of GMP (based on the PIC/S GMP Guide) are noted as being 'practically identical', with only a few minor differences.¹⁵

¹⁴ EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use:
https://ec.europa.eu/health/documents/eudralex/vol-4_en

¹⁵ New Zealand has adopted the Pharmaceutical Inspection Convention / Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice PE 009-8, Parts I, II and Annexes 1 to 3, 6 to 15, 17, 19 and 20 as the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods Part 1: Manufacture of Pharmaceutical Products (2009):
<https://medsafe.govt.nz/regulatory/Guideline/NZRGMPPart1.asp>

54. In New Zealand, the GMP standard applies to all medicinal products, from a common medicine such as Panadol available from a supermarket, through to prescription-only medicines that are also controlled drugs, such as morphine.
55. Some stakeholders proposing to manufacture medicinal cannabis products in New Zealand have indicated that they will follow GMP as the manufacturing standard in order to be able to access international markets, where GMP is a requirement of trade.
56. However, other stakeholders have asked whether it is possible to have the option of applying a different manufacturing standard, such as that adopted by Canada for some health products containing cannabis. We outline the different approaches below.

Current New Zealand approach: Good Manufacturing Practice (GMP)

57. Good Manufacturing Practice is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimise the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. The main risks are: unexpected contamination of products, causing damage to health or even death; incorrect labels on containers, which could mean that patients receive the wrong medicine; and insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.¹⁶
58. GMP covers all aspects of production; from the starting materials, premises and equipment to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process – every time a product is made.
59. The GMP Code describes a set of principles and procedures that, when followed, ensures that the products are produced consistently and are of high quality. GMP aims to build quality into each batch of product during all stages of the manufacturing process to ensure consistency within and between batches of product.

¹⁶ www.who.int/medicines/areas/quality_safety/quality_assurance/gmp/en

60. Manufacturing in accordance with GMP ensures that:
- manufacturing, packing, testing and storage facilities are adequate
 - equipment is suitable for use
 - processes are well defined, validated and under control
 - appropriate quality control testing is completed
 - materials used in manufacture are traceable and of acceptable quality
 - staff are suitably qualified and trained
 - systems are in place to ensure defined processes are followed
 - issues that may pose a risk to product quality are investigated and managed appropriately
 - product complaints are investigated and systems are in place to execute a product recall.

The Canadian approach for prescription medicines (GMP)

61. It is important to note that Canada, like New Zealand, uses Good Manufacturing Practice¹⁷ as the standard under the Food and Drugs Act for medicinal cannabis products that are prescription medicines. Prescription medicines (drugs) can be marketed with health claims and are subject to a pre-market authorisation by Health Canada. In New Zealand, all medicinal cannabis products, including CBD products, have been classified as prescription medicines.

The Canadian approach to non-prescription health products containing cannabis (GPP)

62. In Canada, patients who wish to use 'non-prescription' cannabis products for medicinal purposes require a medical document that authorises the patient to use cannabis for medical purposes. This must be issued by a health care practitioner (which includes medical practitioners and nurse practitioners) for a patient under their care. Manufacturers, importers or suppliers of non-prescription medicines cannot make any health claims and there is no pre-market review of these products for safety or efficacy by Health Canada.¹⁸
63. For these 'non-prescription' cannabis products, Canada has adopted a different framework for the cultivation and processing of cannabis for medical purposes that applies to cannabis intended for both medical and non-medical use. This is referred to as Good Production Practices (GPP).

¹⁷ An interpretation of the requirements for good manufacturing practices to assist industry and health care professionals understand how to comply with GMP has been published by Health Canada: www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0001.html

¹⁸ Health products containing cannabis for non-medical use have only been available since the legalisation of recreational cannabis in Canada in October 2018.

64. This GPP standard in Canada only applies to the commercial cultivation, processing and sale of the 'non-prescription' classes of cannabis – currently to dried cannabis, cannabis oil, fresh cannabis, cannabis plants and cannabis plant seeds. Three new classes of cannabis – edible cannabis, cannabis extracts and cannabis topicals (products for use on skin) – are proposed to be added by October 2019. Canada is also proposing that new regulatory controls will be established to address the public health and safety risks associated with these new classes of cannabis (for example, food safety standards for edible medicinal cannabis products).
65. The requirements for GPP in Canada are set out in its Cannabis Regulations.¹⁹ The requirement to follow GPP applies to a holder of a licence to cultivate, process (manufacture) or sell for medical purposes.
66. The holder of a licence is also required to employ a quality assurance person with appropriate training, experience and technical knowledge to approve the quality of fresh and dried cannabis, cannabis plants and seeds, and cannabis oil prior to making it available for sale, and investigate complaints.
67. The applicant for a licence is required to provide a GPP Report that clearly demonstrates how the GPP requirements will be met.
68. The requirements are specified in Part 5 of the Cannabis Regulations and include requirements for:
 - standard operating procedures to be developed in relation to key operational elements
 - restrictions on the use of pest control products
 - storage and distribution conditions
 - design, construction and maintenance of buildings, air filtration system, and equipment
 - sanitation programme
 - quality assurance
 - investigation of and appropriate action on quality-related complaints
 - methods and procedures for production, packaging, labelling, distribution, storage and approval prior to sale
 - sampling and testing, including composition and pest control products residual limits testing.
69. Part 6 of the Cannabis Regulations sets out the product specifications that must be met before products are approved for sale. Under the Canadian GPP system, fresh and dried cannabis must not contain any substance other than the cannabis, and cannabis oil may contain only the carrier oil. Cannabis oil may be encapsulated.

¹⁹ See Appendix 5 for Part 5 and Part 6 of the Cannabis Regulations or view the full regulations online: <https://laws-lois.justice.gc.ca/eng/acts/C-24.5>

A comparison of Good Manufacturing Practice and Good Production Practices

70. There are a number of areas where the two standards (GMP and GPP) do not align. The GMP guidelines are more detailed, providing principles and interpretation on what must be included in a quality management system to comply, while the GPP standard provides less detail and is therefore more open to interpretation. This difference makes it difficult to directly compare the two standards, with the more detailed requirements of GMP leading to 'minor' differences.²⁰

Validation

71. However, there are two key areas where the two standards differ. The first is that GMP requires a full validation²¹ programme as part of quality assurance, but this is not required under GPP. Validation is critical to demonstrating that products are consistently produced according to standards and specifications, both within and between batches. GMP defines quality measures for both production and quality control and defines general measures to ensure, among other things, that processes necessary for production and testing are clearly defined, validated, reviewed and documented and that the personnel, premises and materials are suitable for the production of pharmaceuticals.
72. These measures are necessary in addition to quality control measures as good quality must be built in to every step of the manufacturing process to prevent errors that cannot be eliminated through quality control of the finished product. Critical steps of the manufacturing process and significant changes to the process are validated. Without validation as part of the quality assurance process, it is impossible to be sure that every product is of the same quality as the product that has been tested in the laboratory.

Stability testing

73. The second area of difference between GMP and GPP is that stability testing is not required under GPP. Under GMP, the stability programme designed in accordance with an internationally recognised standard (such as ICH Q1A to Q1E)²² is required to establish the shelf life (expiry date) of the product.

²⁰ For the high-level summary of the gaps identified between the regulatory requirements for GPP and EU-GMP, see www.cannabiscomplianceinc.com/application-of-gmp-in-the-cannabis-industry

²¹ Validation is a documented programme that provides a high degree of assurance that a specific process, method or system will consistently produce a result meeting pre-determined acceptance criteria. A validation protocol is a written plan stating how validation will be conducted and defining acceptance criteria. For example, the validation protocol for a manufacturing process identifies processing equipment, critical process parameters/operating ranges, product characteristics, sampling, test data to be collected, number of validation runs and acceptable test results.

²² www.ich.org/products/guidelines/quality/article/quality-guidelines.html

Access to export markets

74. Currently Canada is the only jurisdiction to adopt the GPP framework for cultivation and processing of cannabis products (dried cannabis, cannabis oil, fresh cannabis, cannabis plants and cannabis plant seeds, with proposals to add edible cannabis, cannabis extracts and cannabis topicals to the product classes). There are no other jurisdictions that follow GPP, which means a Canadian cannabis firm looking to export is unable to compete internationally because Canadian regulations do not match those of other countries.²³
75. As mentioned earlier, a number of European countries or jurisdictions have adopted pharmaceutical grade controls (GMP) as a requirement for medicinal cannabis products. Internationally the rapid development of the global cannabis-based medicines industry will likely drive the movement towards a requirement for all APIs and finished products to meet pharmaceutical quality standards. These requirements may be the result of and enforced through regional and global medicines policy and regulations, trans-Tasman and global trade agreements, the ratification of pharmacopoeia monographs for cannabis and cannabis-derived medicines, and the various United Nations and International Narcotics Control Board signatory requirements.
76. GMP certification issued by international authorities is recognised by the Ministry of Health. This recognition is based on the GMP assessment systems being compatible with New Zealand expectations. A list of recognised international authorities can be found in Medsafe's *Guideline on the Regulation of Therapeutic Products in New Zealand – Part 4: Manufacture of Medicines*.²⁴

Relative costs of products manufactured to GMP and GPP

77. Canada is the only country that manufactures under both Good Production Practices and Good Manufacturing Practice. We were unable to find any information that directly compared the cost to consumers of the same product under both manufacturing standards.

B3: Proposed quality standards for manufacturing

There are two options for a manufacturing process quality standard.

A - Adopt the current New Zealand approach for manufacturing in accordance with Good Manufacturing Practice (GMP) (Medicines Act) for all medicinal cannabis products.

B - Allow for the manufacture of some medicinal cannabis product dose forms under GMP (Medicines Act) and some medicinal cannabis dose forms under Good Production Practices (GPP) (Misuse of Drugs Act).

²³ Application of GMP in the cannabis industry, 29 March 2019, www.cannabiscomplianceinc.com/application-of-gmp-in-the-cannabis-industry

²⁴ <https://medsafe.govt.nz/regulatory/Guideline/GRTPNZ/manufacture-of-medicines.pdf>

B3: Questions for all:

What is your preferred manufacturing standard for medicinal cannabis products in New Zealand?

If you prefer allowing GPP for some prescription medicines, which dose forms of medicinal cannabis products should be allowed to be manufactured to GPP?

Please indicate your position on the following statements:

‘New Zealand should only allow GMP as the manufacturing standard for medicinal cannabis products’.

‘New Zealand should allow GPP as the manufacturing standard for some forms of medicinal cannabis products (eg, dried cannabis and cannabis oils).’

Do you think medicinal cannabis products should be manufactured to the same standard with regard to consistency and quality as other medicines?

Do you have any additional comments on the proposed options for manufacturing medicinal cannabis products? We are seeking information that compares the cost to the public of the same product under GPP and under GMP. Do you have any information you can share on potential or actual product costs under either option?

B3: Questions for industry:

Do you currently hold a Licence to Manufacture Medicines?

How likely are you to apply for a Licence to Manufacture Medicinal Cannabis Products? Please provide comments on why.

How likely are you to apply for a Licence to Manufacture Medicinal Cannabis Products if the preferred manufacturing standard for all medicinal cannabis products is Good Manufacturing Practice (GMP)?

How likely are you to apply for a Licence to Manufacture Medicinal Cannabis Products under Good Production Practice, GPP, if it is an option for some dose forms (for example, dried cannabis, and cannabis oils)?

What types of medicinal cannabis products do you intend to manufacture?

If you are intending to manufacture medicinal cannabis products to **GMP**, in what timeframe (from the start of the Medicinal Cannabis Scheme) do you think you will have products available for assessment for supply?

If you are intending to manufacture medicinal cannabis products to **GPP**, in what timeframe (from the start of the Medicinal Cannabis Scheme) do you think you will have products available for assessment for supply?

B3: Questions for prescribers:

How likely are you to prescribe a medicinal cannabis product that has been manufactured to Good Manufacturing Practice (GMP)?

How likely are you to prescribe a medicinal cannabis product that has been manufactured to Good Production Practices (GPP)?

B4: Proposed quality standards for API and finished products

78. Generally, the manufacture of a medicinal cannabis product involves the cannabis plant (starting material), which is structurally altered or undergoes processing to obtain the active pharmaceutical ingredient. The API is then used with non-active ingredients (excipients) to manufacture a finished product.
79. Quality standards can be set by requiring certain tests to be undertaken on a product at defined steps of manufacture, and that the product meets the specifications. These tests and specifications for medicinal cannabis products can be set in a monograph – a publication that specifies for a drug the kinds and amounts of ingredients it may contain. Additional standards that are important in the quality of medicines, such as stability and shelf life (see below), are proposed to be requirements for finished products, additional to meeting the Product Quality Standards Monograph.
80. The product quality standards encompass:
 - (a) product specifications – the content of the product at various steps of manufacture, including what is and is not allowed in it
 - (b) dose form requirements – aspects of the product that are appropriate to the particular configuration of the product (eg, that a capsule dissolves at a safe rate)
 - (c) stability and shelf life – the product remains stable (remains within the specifications for the medicine) under the recommended storage and transportation conditions, for the entirety of its shelf life. Note that Good Manufacturing Practice has stability and validation requirements but Good Production Practices do not
 - (d) packaging and labelling – which specify the appropriate storage, packaging, dispensing and use of a product, and make identification of a product clear
 - (e) excipients – the non-active ingredients of a product (excipients) are of suitable and consistent quality.
81. The New Zealand Product Quality Standards Monograph lists the product specifications for medicinal cannabis products (see Appendix 2). These include the kinds and amounts of certain ingredients permitted to be in a product. It does so by defining the applicable tests, methods, specifications and limits.
82. Alternative tests, methods or limits to those stated in the New Zealand Product Quality Standards Monograph can be used if they are scientifically justified.
83. We are consulting on whether and which quality standards may apply to:
 - (a) the starting material (the material received by the first manufacturer from cultivation)
 - (b) the active pharmaceutical ingredients, which produce the effects of the drugs, and/or
 - (c) the finished product.

84. CBD product quality standards would be set by regulations under the Medicines Act 1981, and will apply to medicinal cannabis products that are prescription medicines only and not controlled drugs – currently this is only CBD products. Medicinal cannabis products that are also controlled drugs (eg, THC-based products) will have quality standards specified in regulations under the Misuse of Drugs Act 1975. The quality standards for a finished product will be the same whether it is a prescription medicine only (CBD product) or also a controlled drug (eg, THC-based medicine).

Active pharmaceutical ingredient (API) quality standard

85. An active pharmaceutical ingredient is any substance or mixture of substances that is intended to result in the desired (pharmacological) effect of the product. API derived from starting material may be the granulated flower of the cannabis plant, a plant extract (eg, containing multiple phytocannabinoids like THC or CBD) or an isolated phytocannabinoid (eg, high-purity CBD).
86. It is important to test APIs to confirm the composition (content), and to ensure it is free from contaminants and is of an appropriate quality to be used in the manufacture of medicines. Contaminants might include chemicals that are intentionally added to increase weight or potency (eg, synthetic cannabinoids) but also substances that entered the product unintentionally (eg, heavy metals, moulds and bacteria).
87. As the API is the active ingredient, it is important that there is assurance that it is correctly identified, and that batches are of a consistent and suitable quality to be used in medicines.
88. The proposed quality standard for API is that it meets the New Zealand Product Quality Standards Monograph (see appendix 2). Evidence that the API meets the monograph would be required to be submitted for three verified batches manufactured under GMP. It is likely that there would be a similar requirement under GPP (as over-the-counter medicines are not required to have API manufactured to GMP but the manufacturer may still submit Certificates of Analysis for three batches to verify reproducibility), but as the GPP standard has not been developed, this is to be confirmed.
89. Evidence that API meets the product specifications listed in the New Zealand Product Quality Standards Monograph (Appendix 2) would be required to be submitted after the manufacture of the finished product, in conjunction with evidence that the finished product meets the finished product quality standard and other requirements (see 'Finished product quality standard' below). The testing may have been undertaken by the API manufacturer at release, or by the finished product manufacturer after receiving the API.

B4: Question for industry:

If you are manufacturing API, how likely are you to apply for a licence to manufacture them if API are required to meet quality standards?

B4: Questions for all:

What is your opinion of the following proposal: 'All active pharmaceutical ingredients (API) should be required to meet the requirements of the New Zealand Product Quality Standards Monograph (Appendix 2).' Do you agree/disagree?

Do you have any additional comments on the proposed option for the API product quality standard?

Finished product quality standard

90. Finished products, including CBD products, should have a clearly defined composition of active ingredients and non-active ingredients, which does not change from batch to batch. This means the same dose of active ingredient would be taken each time by the patient. We are not proposing to set limits for the amount of active ingredients allowed in finished products (eg, THC).
91. A finished product would be required to meet the products specifications listed in the New Zealand Product Quality Standards Monograph (Appendix 2). These specifications require identifying and testing the active ingredient(s), the permitted contents of the product and additional requirements important to the quality of a finished product.
92. The finished product quality standard also includes the dose form requirements, packaging and labelling requirements, stability and shelf life requirements and quality of excipients. These requirements are discussed further below.

Dose form

93. A key consideration when prescribing medicines is the dose form. Different dose forms have different advantages and disadvantages, depending on the health conditions being treated. A prescriber will be wanting to ensure each dose form:
 - delivers the active ingredient
 - has a consistent dose.
94. The form in which medicinal cannabis is administered determines the onset, intensity and duration of effects. A finished dose form medicinal cannabis product should behave in a manner appropriate to how it is intended to be taken or administered. Therefore a dose form must meet appropriate specifications; for example, that a capsule dissolves at a safe rate when swallowed.
95. The specifications for the majority of applicable dose forms (eg, tablets, capsules, ointments and creams) are set out in a pharmacopoeia (a set of documented standards for pharmaceuticals). The specifications of dose forms set out

characteristics such as the uniformity of content and the uniformity of dosage units that need to be met for particular dose forms, and the relevant tests to undertake.

96. The dose form requirements are to be incorporated in the quality standards by reference to pharmacopoeial standards, which dictate the requirements, such as how to test that a capsule dissolves at a safe rate. The following pharmacopoeias will likely be referenced in the regulations:
- British Pharmacopoeia (BP)
 - United States Pharmacopoeia–National Formulary (USP–NF)
 - European Pharmacopoeia (Ph Eur).
97. It is proposed that the majority of dose forms would be available at the start of the Scheme, and other dose forms are made available later. Sterile dose forms will only be available under the Scheme as approved or provisionally approved medicines, providing they meet the usual criteria. See below for more information about the different dose forms.

Inhalation products

98. Finished products intended for administration by vaporisation, which meet the quality standards, are proposed under the Scheme. This includes cannabis plant material that is intended to be vaped, but does not include medicinal cannabis products intended to be smoked. While smoking cannabis usually means the product will affect the patient more quickly, it may be difficult to estimate the dose received by individual patients. For this reason and due to well-documented evidence of the harmful effects of smoking, the use of medicinal cannabis products intended for smoking is not supported.²⁵ Cannabis vaporisers heat dried cannabis, or cannabis extracts or resins, creating an inhalable vapour. Vaporisation is associated with less exposure to toxins compared with smoking cannabis.²⁶
99. The pharmacopoeial standard for inhalation products is not directly applicable to cannabis preparations for inhalation. When a medicine is delivered through a device for inhalation, such as an asthma inhaler, the assessment of the device is an integral part in order to establish that the medicine is delivered to the correct place, in a consistent manner.
100. The Medicinal Cannabis Agency may not be able to accurately assess aspects of how a product interacts with a vaping device. For example, these aspects may include how the product reacts at the container closure, how to clean the device, whether dose dumping may occur (where build-up of product suddenly dislodges), how a device performs in hot or cold weather, and whether any contaminants may be leached from the device as it is heated.
101. There are advantages to having an inhalable dose form available to patients. These include the rapid onset of action, the ability of a patient to control and adjust the

²⁵ See the International Narcotics Control Board Annual Report 2018 www.incb.org/incb/en/publications/annual-reports/annual-report-2018.html and see also Therapeutic Goods Administration Guidance for the use of medicinal cannabis in Australia – Overview (December 2017) www.tga.gov.au/publication/guidance-use-medicinal-cannabis-australia-overview

²⁶ www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-and-smokeless-tobacco

dose according to need, and that it is a beneficial method of delivery for patients who have difficulty swallowing.

102. It is proposed that the products that can be vaped would be made available in the interest of patient access to medicinal cannabis products. The product that is to be vaporised would be assessed by the Medicinal Cannabis Agency. The inhalation device may be assessed as well; however, the methods of doing so need to be further developed. There would be no requirement for a device to be assessed at the implementation of the scheme. However, this may change in the future.

Modified-release dose forms

103. A modified release dose form, including patches placed on the skin (transdermal), is a preparation where the rate and/or place of release of active ingredient is different from that of a conventional-release dose form administered by the same route. This deliberate modification is achieved by a special formulation design and/or manufacturing method. Modified-release dose form includes delayed-release, prolonged-release and pulsatile-release (rapid release after a defined lag time) dose forms.
104. It is proposed that modified-release dose forms would not be available under the Medicinal Cannabis Scheme if they are unapproved medicines. This dose form is currently not able to be sufficiently assessed against quality standards only, in the absence of any clinical data (eg, clinical trials). However, modified-release dose forms would be available if they are approved or provisionally approved by the Ministry of Health.

Sterile dose forms

105. Injectables, and ear and eye preparations are required to meet tests that determine they are sterile. Sterile dose forms like these are not able to be sufficiently assessed against product quality standards only, in the absence of any clinical data (eg, clinical trials). It is proposed that medicinal cannabis products that are required to be sterile are not allowed to be accessed as an unapproved medicine so will only be available under the Scheme if they are approved or provisionally approved by the Ministry of Health.

Edible dose forms

106. The Food Act 2014 excludes anything that is used only as a medicine or is a controlled drug or psychoactive substance. Food containing medicinal cannabis will not be allowed under the Scheme.

Other types of product

107. There is no separate regulatory pathway for cannabis-based dietary supplements, natural health products or nutraceuticals. A producer who wants to manufacture these types of product would have to meet the requirements of the Medicinal Cannabis Scheme, with all products being prescription-only.

Packaging and labelling

108. Labelling provides information on the appropriate storage, dispensing and use of a product, and makes identification of a product clear and unambiguous.

109. Labelling is essential for regulatory control where the safe and appropriate use is identifiable and enables return and recall of a product when necessary.
110. Appropriate controls on labelling of medicines and controlled drugs are already specified in regulations of the Medicines Act 1984, Misuse of Drugs Act 1975 and the Ministry of Health Guideline on the Regulation of Therapeutic Products in New Zealand. It is proposed that the packaging and labelling of medicinal cannabis products follow established packaging and labelling standards. For example, the total cannabinoid content of the finished dose must be stated on the medicine label.

Stability and shelf life

111. The purpose of stability data is to establish how a product varies with time under a variety of environmental conditions such as temperature, humidity and light.
112. A manufacturer would be required to provide evidence that the product remains stable under the recommended storage and transportation conditions for the shelf life of the product.
113. Appropriate controls on stability and shelf life are already specified in guidelines by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).²⁷ It is proposed that medicinal cannabis products follow established stability and shelf life guidelines.

Excipients

114. Excipients are the ingredients of the drug that are inactive but are important in the formulation of the product in its finished dose form. Examples are preservatives, flavours, fillers and emulsifiers.
115. Controlling the quality of the excipients is important as they can make up the majority of the finished product. The overall quality of the product will be poor, or it could even be harmful, if there is no quality standard for excipients. There are two ways to meet the standard when choosing excipients:
 - (a) use of excipients specified in a pharmacopoeia, and providing evidence according to the test methods and limits specified in the relevant pharmacopoeia. Where a pharmacopoeial monograph is used, any change to the test, test methods or limits should be scientifically justified, and/or
 - (b) use of excipients that are not specified in a pharmacopoeia. When non-pharmacopoeial excipients are used, the manufacturer should provide a description of the tests, test methods and limits applied and scientifically justify how these assure the quality and consistency of the ingredients used.
116. In all cases, the specifications must characterise the excipients and ensure that all batches are of suitable and consistent quality for use in the manufacture of the medicines.

²⁷ www.ich.org/home.html

The New Zealand Finished Product Quality Standards

117. The New Zealand Product Quality Standards Monograph (Appendix 2) lists the product specifications, including the tests, methods and limits for what an API or finished medicinal cannabis product may contain.
118. Starting material may have quality standard requirements depending on the outcome of consultation (see Section B1). If there is a quality standard requirement, it will consist of:
- (a) the New Zealand Product Quality Standards Monograph.
119. The proposed API quality standard consists of:
- (a) the New Zealand Product Quality Standards Monograph.
120. The proposed finished product quality standard consists of:
- (a) the New Zealand Product Quality Standards Monograph
 - (b) dose form requirements
 - (c) packaging and labelling requirements
 - (d) stability and shelf life requirements
 - (e) excipient requirements.

Table 2: Proposed product quality standard requirements

Type of material	Proposed product quality standards required to be met				
	Monograph	Packaging and labelling	Excipients	Dose form requirements	Stability and shelf life
Starting material	Dependent on outcome of consultation	No	No	No	No
Active pharmaceutical ingredients (API)	Yes	No	No	No	No
Finished product	Yes	Yes	Yes	Yes	Yes

B4: Questions for all:

Please indicate your position on the following statement:

'It is proposed that the finished product quality standard should include the dose form requirements.'

Should there be a limit on the amount of active pharmaceutical ingredient in each dose? If yes, what do you think the limit per dose should be?

Do you have any additional comments on the proposed dose form requirements?

B4: Questions for prescribers:

What types of products would you be most likely to prescribe?

(eg, Dried cannabis, Cannabis oils, Ointments or creams or topical balms, Tablets or capsules or other oral dose forms, Transdermal patches, Other)

If you were to prescribe medicinal cannabis products, which route of delivering the medicine would you be most likely to support?

(eg, Oral; Inhalation; Patch (transdermal); Creams or ointments (transdermal); Under the tongue (sublingual), or Other)

B4: Questions for industry:

How likely are you to apply for a licence to manufacture based on the requirements of the proposed quality standard for finished products?

Do you agree that the proposed finished product quality standard should include the above requirements?

Testing to meet the product quality standards

121. Testing to provide evidence that the product meets the defined chemical properties and structure (the quality standards) should be undertaken using approved, validated and robust laboratory methods. The test laboratory undertaking the tests should be appropriately accredited and attest that validated methods will be used. The release certificate is provided by a certified laboratory.
122. Each batch of API and finished products produced under the scheme would be expected to be consistent and meet the relevant quality standards, if set.

123. Batches of material would be required to be tested and results to verify that they meet the relevant quality standards, before they are allowed to be released for supply. The facility that is releasing the material will need to provide evidence that it has a validated quality assurance programme and provide test results confirming the materials meet the product quality standards. The process comprises:
- (a) checking production processes performed by the designated quality assurance personnel, which shows that the batch complies with the quality standards
 - (b) testing each batch of API and finished products in accordance with the specifications set out in the New Zealand Product Quality Standards Monograph (Appendix 2)
 - (c) testing for, and submitting evidence supporting, compliance with the additional requirements set for finished products (stability and shelf life, packaging and labelling etc).
124. Testing would be required for each batch of materials to be undertaken by an accredited laboratory using approved, validated and robust testing methods. The results are to be provided in the form of a Certificate of Analysis (CoA). A CoA certifies the quality of the product and demonstrates that the batch of product conforms to defined specifications (see Appendix 2).
125. Certificates of analysis are an essential part of the supply and manufacturing chain and are how the manufacturers under the Scheme will demonstrate that their products meet the quality standards.
126. A CoA should contain the following information:
- (a) name of the API or finished product or excipient
 - (b) batch number
 - (c) release date
 - (d) expiry date
 - (e) a list of each test performed in accordance with the monograph (test conditions and parameters)
 - (f) the acceptance limits for each test and results obtained
 - (g) dated signature by authorised personnel
 - (h) name of the laboratory that undertook the analysis
 - (i) name of the company the analysis is undertaken for.
127. CoAs are required to prove the medicinal cannabis products meet the release specification from a laboratory or laboratories certified by the Ministry of Health for Good Manufacturing Practice, or from an International Accreditation New Zealand²⁸ (IANZ) accredited test at a laboratory accredited to International Organization for Standardization (ISO) 17025.²⁹

²⁸ Accreditation by IANZ is the international process for assessing and recognising the technical competence and the effective quality processes of laboratories, among other services.

²⁹ 'ISO 17025 General requirements for the competence of testing and calibration laboratories' is the main ISO standard used by testing and calibration laboratories. In most countries, ISO/IEC 17025 is the standard for which most laboratories must hold accreditation in order to be deemed technically competent.

128. Evidence supporting compliance with the additional requirements set for finished products (stability and shelf life, packaging and labelling etc) must be submitted in accordance with the pharmacopoeia, ICH guidelines and/or regulations that they refer to.

B4: Questions for industry:

Please indicate your position on the following proposal:

'Batch testing should be required to provide evidence that the product meets the requirements of the product quality standard.'

Do you have any additional comments on the proposed testing requirements?

After meeting the quality standards

129. A finished product will be permitted for distribution in New Zealand under a Misuse of Drugs Act Licence to Supply Unconsented Medicinal Cannabis Products or a Medicines Act Licence to Sell Medicines by Wholesale for CBD products. These licences can be issued to a person or company that wishes to distribute medicinal cannabis products in New Zealand. Additional products could be added to the appropriate licence by submitting an amendment request to the Medicinal Cannabis Agency, along with Certificates of Analysis that demonstrate that the product meets the quality standards specified in the proposed regulations. If the product meets the quality standards, a Licence to Supply Unconsented Medicinal Cannabis Products or Licence to Sell Medicines by Wholesale would allow the distribution of that particular product by the licence holder.
130. All medicinal cannabis products will be required, as a minimum, to meet the quality standards regardless of their distribution status in New Zealand; for example, approved for distribution by the Ministry of Health, provisionally approved or unapproved.³⁰

³⁰ However a specialist may prescribe a medicinal cannabis product that does not meet the quality standards after obtaining approval from the Ministry of Health.

Part C: Licensing under the Scheme

131. This section sets out the proposed licensing regime for the commercial cultivation of cannabis and for manufacturing and supply of medicinal cannabis products. It also includes information on the transition from current cultivation licences for scientific and medical research and how the scheme interfaces with the current regulations.
132. The proposed licensing regime is designed to help New Zealand meet our international obligations. We are required to control the cultivation, distribution, and use of medicinal cannabis in a way that is consistent with the licit (legal) uses allowed for in the Single Convention on Narcotic Drugs 1961. This is also required for other controlled drugs and medicines.
133. A summary of the current and additional proposed licences are set out in Table 3 as a useful reference when reading this section.

Table 3: Current and proposed licences

Licence name	Legislation issued under	Also known as	Current licence/ proposed licence	Activities covered by the licence
Licence to Cultivate a Prohibited Plant	Misuse of Drugs Act 1975	<ul style="list-style-type: none"> Cultivate Licence Cultivate Research Licence 	Current	The cultivation of cannabis for scientific or medical research. Does not allow cultivation for a commercial purpose.
Licence for Industrial Hemp General Licence	Misuse of Drugs Act 1975	Industrial Hemp Licence	Current	The cultivation of low-THC cannabis for industrial purposes. Does not allow cultivation for medicinal purposes.
Licence for Industrial Hemp Research and Breeding Licence	Misuse of Drugs Act 1975	Industrial Hemp Research Licence	Current	The cultivation of low-THC cannabis for breeding research purposes related to industrial hemp. Does not allow cultivation of hemp for breeding research for medicinal purposes.
Licence to Manufacture Medicines	Medicines Act 1981		Current	The manufacture of medicines from starter material to finished product for therapeutic use in humans.
Licence to Pack Medicines	Medicines Act 1981		Current	The packing of medicines into their final packaging.

Licence name	Legislation issued under	Also known as	Current licence/ proposed licence	Activities covered by the licence
Licence to Sell Medicines by Wholesale	Medicines Act 1981	Wholesale Licence	Current	The distribution of medicines by wholesale.
Licence to Deal in Controlled Drugs	Misuse of Drugs Act 1975	Licence to Deal	Current	The possession of a controlled substance. The processing/extraction of cannabis. The manufacture of a product for scientific purposes. This does not include manufacture for use in humans, including packaging.
Licence to Possess Controlled Drugs	Misuse of Drugs Act 1975	Licence to Possess	Current	The possession but not supply of a controlled substance.
Licence to Import Controlled Drugs	Misuse of Drugs Act 1975	Import Licence	Current	The import of one consignment of cannabis product (up to four products per licence).
Licence to Export Controlled Drugs	Misuse of Drugs Act 1975	Export Licence	Current	The export of one consignment of cannabis product (up to four products per licence).
Licence to Cultivate Medicinal Cannabis	Misuse of Drugs Act 1975		Proposed new	The cultivation of medicinal cannabis for either scientific research or commercial purposes.
Licence to Manufacture Medicinal Cannabis Products	Misuse of Drugs Act 1975		Proposed new	The manufacture of medicinal cannabis products from starter material to finished product (including packaging) for therapeutic use in humans.
Licence to Pack Medicinal Cannabis Products	Misuse of Drugs Act 1975		Proposed new	The packing of medicines that are controlled drugs into their final packaging.
Licence to Supply Unconsented Medicinal Cannabis Products	Misuse of Drugs Act 1975	Licence to Supply	Proposed new	The supply by wholesale of medicinal cannabis products that have been verified as meeting the product quality standards.

C1: Overview

134. The Medicinal Cannabis Agency will license activities relating to the commercial cultivation of cannabis and the manufacture and supply of medicinal cannabis products. The licensing of these activities is to ensure that products available under the Scheme meet the specified quality standards. It also will help manage the risk of diversion of cannabis into the illicit market and to enable tracking and reporting to meet International Narcotics Control Board requirements. Licences will be issued for one year and can be renewed. Each renewal would be for an additional 12 months.
135. Licences would be issued under the Misuse of Drugs Act 1975 for the cultivation of cannabis. Licences for the supply of medicinal cannabis products will be issued under the Medicines Act 1981 for CBD products, and under the Misuse of Drugs Act for all other medicinal cannabis products (see Table 3 above for more information).

C2: International Narcotics Control Board reporting requirements

136. As a signatory to the Single Convention on Narcotic Drugs 1961, New Zealand is required to provide the following information to the International Narcotics Control Board:
 - quarterly statistics of imports and exports of narcotic drugs
 - annual estimates of requirements for narcotic drugs and cultivation of the cannabis plant
 - annual statistics of production, manufacture, consumption, stocks and seizures of cannabis.
137. In order that these requirements can be met, licence holders will be required to keep the relevant records and report the information to the Ministry of Health as a general licence condition.

C3: General requirements for all licences issued under the Scheme

138. There are general requirements that will apply when making an application for a licence issued under the Medicinal Cannabis Scheme. The application will only be considered if the requirements are met.
139. General information and contact details need to be supplied for the applicant and, in the case of a body corporate or partnership, the name of every director or partner and the name and contact details of every person nominated to be a 'responsible person'.

140. A 'responsible person' is an individual authorised to control the activities for which the licence is sought. There may be more than one responsible person nominated for a licence application. This person or these people must be familiar with, and have the expertise to comply with, the obligations imposed by the licence and the regulations. Responsible persons must have knowledge of the entire operation and procedures, particularly the security aspects of the whole enterprise.
141. A 'responsible person' is usually a senior-level member of the organisation with hands-on responsibilities for staff, operational procedures and security. A responsible person must be resident in New Zealand and be over 18 years old.
142. In addition, all applicants, company directors, partners in a partnership and 'responsible persons' need to:
- (a) have the capacity to comply with the conditions on the licence
 - (b) not have had a previous licence issued under the Misuse of Drugs Act revoked
 - (c) undergo vetting by the New Zealand Police Vetting Service
 - (d) have not been convicted of:
 - (i) an offence against the Misuse of Drugs Act 1975 or of any other drug-related offence³¹
 - (ii) a crime involving dishonesty within the meaning of the Crimes Act 1961
 - (iii) an offence outside New Zealand that, if committed in New Zealand, would fall within (i) or (ii).
143. Please note: convictions covered under the Criminal Records (Clean Slate) Act 2004 may not need to be disclosed. For more information, please visit the Ministry of Justice website (www.justice.govt.nz/criminal-records/clean-slate) or seek legal independent advice.
144. The completed application must include details of the premises of the proposed licensed activity, including the location's geographical coordinates.
145. An important aim of the Scheme is to minimise the risk of medicinal cannabis being sold or used illegally (diversion). Therefore all applications must include detailed security plans on how this risk will be minimised at every step of the process, from cultivation of seed to final product, and also outline arrangements for the destruction of any waste material.
146. Audits of the site where medicinal cannabis cultivation, manufacturing or other relevant activities will take place will be required. These audits will verify that security and other appropriate arrangements are in place before any activities commence.

³¹ See section 14(4) of the Misuse of Drugs Act 1975

http://www.legislation.govt.nz/act/public/1975/0116/latest/DLM436101.html?search=qs_act%40bill%40regulation%40deemedreg_misuse+of+drugs+act_resel_25_h&p=1&sr=1

C3: Questions for industry:

Are any of the proposed licensing requirements likely to impact on your ability to apply for a licence? If yes, please provide details.

Do the proposed licensing requirements create equity issues about who is able to enter the sector? For example, are there any barriers to obtaining a licence to cultivate for growing on Māori land?

C4: Licence to Cultivate Medicinal Cannabis (proposed)

147. Licensing requirements for the proposed Licence to Cultivate Medicinal Cannabis include those listed as general requirements as well as additional requirements specific to the activity of cultivation.
148. The proposed Licence to Cultivate Medicinal Cannabis would be issued under the Misuse of Drugs Act for a period of one year and could be renewed. Each renewal would be for an additional 12 months.
149. Activities considered to be part of cultivation are:
 - (a) possession of plant material and seed for the purposes of the activities specified in the licence
 - (b) growing
 - (c) harvesting (including trimming)
 - (d) drying of plant material and seed
 - (e) storing of plant material and seed
 - (f) supply of plant material and seed to another holder of an appropriate licence.
150. Further processing of plant material and supply as a final product or active pharmaceutical ingredient (ie, wholesale or retail) are not considered to be part of the cultivation activity. This includes processing (for example, extraction or grinding) for testing.
151. A fee would be charged for assessing an application for a proposed Licence to Cultivate Medicinal Cannabis. The fee would be higher for large-scale cultivation (greater than 200 square metres) than small-scale cultivation (200 square metres or less). This proposed division in size is based on the same division implemented in Canada and reflects the lower audit costs for smaller cultivators.

152. The completed licence application would need to include:
- evidence that demonstrates that the cultivation of cannabis is for the purpose of either or both:
 - supply to the holder of an appropriate manufacture licence (evidence of contractual arrangements would be required)
 - medical or scientific research
 - the following details of the proposed cultivation activity:
 - types and cultivars (specific plant varieties) of cannabis – including the concentrations of particular cannabinoids (eg, CBD, THC)
 - size of cultivation area and number of plants
 - period of cultivation/production
 - details of the source material (seeds/cultivars/germplasm etc)³²
 - origin of the source material.
153. The security requirements for the land and/or buildings used for cultivation are dependent on the THC level of the cannabis grown. Licensees that plan to grow only low-THC cannabis, which is an approved cultivar (a specific plant variety) under the Misuse of Drugs (Industrial Hemp) Regulations 2006 (the Industrial Hemp Regulations), will be required to meet lesser security requirements than licensees who plan to grow high-THC cannabis, or a combination of low-THC and high-THC cannabis.
154. Those who wish to grow low-THC cannabis that is not an approved cultivar will be required to meet the security requirements set for high-THC cannabis as the THC content cannot be verified. Applications for new approved cultivars that meet the requirements of the Industrial Hemp Regulations can be made using the current process.
155. All cultivation of cannabis is controlled under the Single Convention on Narcotic Drugs 1961, except for cannabis cultivated exclusively for fibre and seed (ie, industrial hemp). In line with other jurisdictions, mixed use of crops (ie, separating cannabis from the plant for medicinal or scientific research purposes and using the remainder for industrial purposes) will not be permitted. Cannabis grown for medicinal purposes will need to be grown and used solely for those purposes.
156. Currently, the Industrial Hemp Regulations allow the supply of hemp seeds only to anyone authorised by a licence under the Industrial Hemp Regulations to procure hemp seeds.

³² Germplasm is living tissue from which new plants can be grown. It can be a seed or another plant part – a leaf, a piece of stem, pollen or even just a few cells that can be turned into a whole plant.

157. A holder of an Industrial Hemp Licence under the Industrial Hemp Regulations could not provide hemp for medicinal cannabis purposes under the Industrial Hemp Licence.³³ A Licence to Cultivate Medicinal Cannabis must be held for any cannabis to enter the medicinal manufacture and supply chain. A person may hold a Licence to Cultivate Medicinal Cannabis for one crop and an Industrial Hemp Licence for another crop, but will have to maintain physical separation between the two crops and comply with the applicable cultivation and security requirements.³⁴
158. Note that the proposed Misuse of Drugs Act Licence to Cultivate Medicinal Cannabis does not confer any cultivar intellectual property rights (including commercial rights) on the licence holder.³⁵ There is an established process for this through the Intellectual Property Office of New Zealand.

C4: Questions for industry and researchers:

Are any of the proposed licensing requirements likely to impact on your ability to apply for a licence to cultivate? If yes, please provide details.

What are your views on the proposal to allow growers of industrial hemp to be able to supply seeds to medicinal cannabis licensees and industrial hemp licensees? Please explain why/why not.

What are your views on the proposal to allow medicinal cannabis licensees to be able to supply seeds to industrial hemp licensees? Please explain why/why not.

Is the proposed 200 m² cultivation area an appropriate cut-off level between small-scale and large-scale cultivation? Please provide comment.

How many cultivation sites are you planning and what would be the average size of each cultivation area?

³³ Industrial hemp is approved varieties of *Cannabis sativa* that have a THC content below 0.35 percent, and seeds harvested from plants of that kind. Hemp means cannabis plant, seed or fruit, while a hemp product is defined as a product of a kind that is derived, in whole or in part, from industrial hemp.

³⁴ The requirements for separating the crops may change depending on what is being cultivated; for example, low-THC crops will need stricter separation from high-THC crops than different low-THC crops will need from each other.

³⁵ Intellectual property rights protect the expression of your idea in something you have made or created.

C5: Declaration of illicit (illegal) New Zealand seed

159. Cultivators who have access to illicit (illegal) New Zealand cannabis seed will be able to legally use that seed through making a declaration. The cultivator will be required to report the amount of seed and supply any other known details but will not be required to disclose where or how the seed was acquired. There will be a fee placed on the declaration to cover the costs of administration. There may be limits placed on the amount of domestic seed that can be declared and the number of declarations. The declaration of illicit seed is not intended to be an ongoing source of seed for a cultivator.

C5: Question for all:

Should there be limits on the amount of seed or the number of declarations that could be allowed? Please provide an explanation for your view.

C6: Transition from current cultivation licences

160. Licences to Cultivate a Prohibited Plant are currently issued to allow the cultivation of cannabis for the purpose of medical or scientific research. Under this licence, it is a general requirement that all cannabis plants and cannabis products are destroyed at the end of the research programme. In some instances, the research that is being conducted is a breeding programme to identify or enhance specific characteristics of the cannabis plant.
161. In these situations, it is the intention to allow the transition of plants from a licence holder's 'Licence to Cultivate a Prohibited Plant' to their 'Licence to Cultivate Medicinal Cannabis' cultivation licence under the Medicinal Cannabis Scheme without having to destroy all of these specialty breed plants. However, this is not intended to allow those already licensed to cultivate under a research licence to grow a large number of plants in preparation for the transition to the Scheme. Only a limited of plants necessary to maintain the cultivar will be allowed to transition. A cultivar is a selected form of the plant with some desirable characteristics. All other plants resulting from the research will still need to be destroyed.
162. The possession of a current Licence to Cultivate a Prohibited Plant does not automatically confer the right to obtain a Licence to Cultivate Medicinal Cannabis under the Scheme. A new application would be required, which would then be assessed against the requirements of the regulations at the time of submission.

C6: Question for industry and researchers:

What would be the minimum number of plants you require to retain in order to maintain specific cultivars, when moving from a research to a commercial cultivation operation? Please provide justification for numbers suggested.

C7: Licence to Manufacture

163. Medicines manufactured in New Zealand for human consumption can only be manufactured by the holder of a Licence to Manufacture. A current Licence to Deal in Controlled Drugs under the Misuse of Drugs Act does not allow the holder to manufacture medicines for human consumption.
164. The manufacturing activity includes any manipulation to the cannabis plant material not considered to be part of cultivation, including, for example, extracting and developing into a dose form for medicinal purposes.
165. Manufacture also includes the packaging of the final product. Therefore even if the final product does not differ from that which is supplied by the cultivator, a manufacture licence would still be necessary for the packaging of that product for distribution.
166. Licences to Manufacture Medicinal Cannabis Products under Good Manufacturing Practice would be issued under the Medicines Act, and Licences to Manufacture Medicinal Cannabis Products under Good Production Practices would be issued under the Misuse of Drugs Act, except for CBD products, which would be issued under the Medicines Act.
167. Manufacturers wanting to manufacture medicines to be considered for approval or provisional approval for distribution by the Ministry of Health will be required to manufacture to Good Manufacturing Practice, which is unchanged from the current requirement.
168. No matter which standard is used, manufacturers making unapproved medicinal cannabis products (other than CBD products) to be supplied to market would need a Licence to Supply Unconsented Medicinal Cannabis Products issued under the Misuse of Drugs Act. To obtain this licence, all products would have to, as a minimum, meet the product quality standards set by the regulator.

Licence to Manufacture Medicines using Good Manufacturing Practice as the manufacturing standard

169. Licences to Manufacture using GMP as the manufacturing standard would be issued under the Medicines Act for one year, with renewals for an additional year at a time. This licence is issued by the Ministry of Health and includes a number of requirements, including onsite audits (see <https://medsafe.govt.nz/Medicines/manufacturing.asp>). When manufacturing controlled substances, the manufacturer would also require an appropriate controlled drug licence under the Misuse of Drugs Act.
170. Currently two types of licences are issued under the Medicines Act.
- The Licence to Manufacture Medicines includes all processes involved with manufacturing a medicine from starter material to the finished packaged product.
 - The Licence to Pack Medicines includes only the packaging/repackaging of final product.

Licence to Manufacture Medicinal Cannabis Products using Good Production Practices as a manufacturing standard

171. Licences to Manufacture using GPP as a manufacturing standard would be issued under the Misuse of Drugs Act. This licence would be issued by the Medicinal Cannabis Agency for one year, with renewals for an additional 12 months at a time.
172. As with the licences issued under the Medicines Act, two different licences would be offered.
- The Licence to Manufacture Medicinal Cannabis Products would include all processes involved with manufacturing a medicinal cannabis product from starter material to the finished packaged product.
 - The Licence to Pack Medicinal Cannabis Products would include only the packaging of product. This is appropriate for licence holders who plan to import product that needs repackaging for the New Zealand market.
173. Licensing requirements for the licences to manufacture include those listed as general requirements as well as separate requirements specific to the activity of manufacture.
174. The completed licence application must include:
- the planned dose forms to be manufactured
 - details of the manufacturing processes to be used.
175. These licences will include the assessment of both the manufacturing practices and the security arrangements of the manufacturer. As this licence is issued under the Misuse of Drugs Act, it will include the ability for the licence holder to possess controlled drugs. No further controlled drug licence will be required.

C7: Question for industry:

Are any of the proposed licensing requirements likely to impact on your ability to apply for a licence to manufacture? If yes, please provide details.

C8: Licence to Sell Medicines by Wholesale

176. For distribution by wholesale of products that meet the definition of a CBD product, a Licence to Sell Medicines by Wholesale issued under the Medicines Act will continue to be required but with an additional condition that any CBD products supplied must, as a minimum, meet the finished product quality standard. Evidence must be provided to the Medicinal Cannabis Agency that verifies that the product meets the finished product quality standard before the product can be added to the licence for supply.
177. All medicinal cannabis products approved or provisionally approved by the Ministry of Health will still be distributed under the Licence to Sell Medicines by Wholesale and a Licence to Deal in Controlled Drugs.

C8: Question for industry:

Will the requirement for products to meet the finished product quality standard impact on your ability to apply for a licence to sell medicines (CBD products) by wholesale? If yes, please explain why.

C9: Proposed Licence to Supply Unconsented Medicinal Cannabis Products

178. A Licence to Supply Unconsented Medicinal Cannabis Products would be issued under the Misuse of Drugs Act for a period of one year. Licences will be issued for one year and can be renewed. Each renewal would be for an additional 12 months.
179. For distribution of any unapproved non-CBD, medicinal cannabis product, a Licence to Supply Unconsented Medicinal Cannabis Products would be required. For each product for distribution on this licence, evidence must be provided to the Medicinal Cannabis Agency to verify that the product meets the finished product quality standard.

180. This may mean that some existing wholesalers of controlled drugs would need both a Licence to Deal in Controlled Drugs and a Licence to Supply Unconsented Medicinal Cannabis Products if they wish to supply both medicinal cannabis products and non-cannabis based controlled drugs by wholesale. In this case, the fees for the Licence to Supply Unconsented Medicinal Cannabis Products would be adjusted to ensure that the wholesaler is not charged twice for an assessment of its security procedures for controlled drugs.
181. A Licence to Deal in Controlled Drugs under the Misuse of Drugs Act will not allow the distribution of unapproved medicinal cannabis products.

C9: Questions for industry:

Are the above requirements likely to impact on your ability to apply for a Licence to Supply Unconsented Medicinal Cannabis Products under the Misuse of Drugs Act? If yes, please explain why.

Do you have any additional comments on the proposed options for supplying medicinal cannabis products?

C10: Interface with existing Misuse of Drugs Act and Medicines Act licences

182. The intention is to have minimal overlap in the activities that are licensed by the Scheme compared with licences issued for the purpose of dealing in non-cannabis based controlled drugs. However, in some situations a licence holder will be required to have a licence for medicinal cannabis products in addition to a licence for other controlled drugs.
183. For example, holders of a Licence to Deal in Controlled Drugs (issued under the Misuse of Drugs Act) and a Licence to Sell Medicines by Wholesale (issued under the Medicines Act) are able to supply non-cannabis based controlled drugs. However, in order to supply medicinal cannabis products (excluding CBD products), they would also require a Licence to Supply Unconsented Medicinal Cannabis Products. A Licence to Deal in Controlled Drugs would enable the licence holder to supply products that have been assessed and meet the product quality standards under the Medicinal Cannabis Scheme.
184. In situations where an applicant requires multiple licences, a reduction in fees may apply. This potential reduction applies if the Medicinal Cannabis Agency is reasonably satisfied that the information and documents provided for each application are sufficiently similar to reduce the work involved in assessing them.

C11: Assessment of products against the quality standard

185. Medicinal cannabis products can be supplied under the Medicinal Cannabis Scheme if they meet the quality standard. This condition would be a requirement of a Licence to Supply Unconsented Medicinal Cannabis Products (for non-CBD products) or a Medicines Act Licence to Sell Medicines by Wholesale (for CBD products). Suppliers (who may also be manufacturers or importers) who introduce a product into the supply chain would be required to provide information to the Medicinal Cannabis Agency to demonstrate that the product meets the finished product quality standard.
186. The product is required to meet the New Zealand Product Quality Standards, which includes the New Zealand Product Quality Standards Monograph in addition to specific requirements around dose form, packaging, labelling, stability and shelf life.
187. It is proposed that a fee will be charged to cover the cost of the product assessment, with each product requiring a separate assessment. Note that products being submitted to be considered for approval or provisional approval by the Ministry of Health will not require assessments against the product quality standards.

C12: Licences to import and export

Importing and exporting medicinal cannabis products

188. The below requirements apply to all medicinal cannabis products (including CBD). All imported or exported medicinal cannabis products would be required to be manufactured to the same standards as products manufactured in New Zealand, as a minimum, and meet the product quality standards of the Medicinal Cannabis Scheme.
189. Exporting all Ministry of Health approved medicinal cannabis products when supplying for retail sale will require a Licence to Sell Medicines by Wholesale. These products can be exported without a licence, provided they are not supplied directly to a patient.
190. Currently, New Zealand does not allow the export of an unapproved prescription medicine. We propose to allow the export of unapproved medicinal cannabis products that meet quality standards under the Scheme. These products would also need to meet the requirements of importing countries.
191. We are proposing to allow standardised, packaged and labelled raw cannabis that meets the relevant New Zealand product quality standards, and that can be exported into medicinal markets overseas under the conditions of an export licence.

192. However, in order to continue to meet our international obligations under the Single Convention on Narcotic Drugs 1961, and to minimise the risk of diversion, we are proposing, like Canada and Australia, to not allow the export of unprocessed or bulk raw cannabis.
193. The Medicines Act does not provide for licences to import medicines specifically. However, holders of Licences to Sell Medicine by Wholesale can import medicines if supplying to others for retail sale.

Additional requirements for medicinal cannabis products (non-CBD)

194. All medicinal cannabis products are controlled drugs, except for CBD products.³⁶
195. Because they are controlled drugs, licences issued under the Misuse of Drugs Act 1975 (MoDA) are required to import and export finished medicinal cannabis products. Each licence to import or export under MoDA can only be issued for a single delivery of products (a consignment). More details on specific requirements for importing and exporting are below.

Exporting – medicinal cannabis products (non-CBD)

196. Requirements for exporting non-CBD medicinal cannabis products will include (but are not limited to):
 - holding a licence to supply, deal, possess or cultivate under the Misuse of Drugs Act. This licence must specify the product details and quantity of every substance intended for export
 - meeting the requirements of the Misuse of Drugs Act and the Misuse of Drugs Regulations and the importing country's legislation
 - producing a certificate from the relevant authority of the importing country. Whether the importing country allows the import will depend on the classification of the medicinal cannabis product in that country
 - as a minimum, medicinal cannabis products for export must meet the product quality standards set under the Scheme and be manufactured to the manufacturing process standards set under the Scheme.

³⁶ Cannabidiol and CBD products with up to 2 percent of other cannabinoids that are specified substances are no longer controlled drugs under the Misuse of Drugs Act 1975 (but they remain as medicines regulated under the Medicines Act).

C12: Questions for industry:

How likely are you to export medicinal cannabis products based on the above proposals?

If allowed, what type of medicinal cannabis product would you be interested in exporting? (eg, API, starting material)

What finished dose forms of medicinal cannabis products are you interested in exporting?

C12: Question for all:

Should the export of unprocessed or bulk raw cannabis be allowed? Please explain why/why not,

Importing – medicinal cannabis products (non-CBD)

197. Requirements for importing non-CBD medicinal cannabis products will include (but are not limited to):

- holding a licence to supply, deal, possess or cultivate under the Misuse of Drugs Act. This licence must specify the product details and quantity of every substance intended for import
- meeting the requirements of the Misuse of Drugs Act, the Misuse of Drugs Regulations and the exporting country's legislation
- imported products for distribution in New Zealand must be manufactured to the same standards that apply to New Zealand manufactured products (with appropriate documentation from a GMP-certified lab). The importer must also submit information to the Medicinal Cannabis Agency that demonstrates that their product meets the product quality standards that have been set under the Scheme.

C12: Questions for industry:

Based on the proposals outlined in Section C12, how likely are you to import medicinal cannabis products?

Are these requirements likely to impact on your ability to apply for a Licence to Supply Unconsented Medicinal Cannabis Products under the Misuse of Drugs Act? If yes, please explain why.

What forms of medicinal cannabis products are you interested in importing?

Personal importation of medicinal cannabis products

198. Personal importing of medicinal cannabis products that are controlled drugs is allowed if you arrive in New Zealand carrying them on you or in your luggage, provided that on arrival you declare the controlled drugs to the New Zealand Customs Service.
199. You must also demonstrate that the drug is required for treating a medical condition for you or for someone under your care who is travelling with you, that the drug has been lawfully supplied to you in the country of origin and that it is no more than one month's supply.
200. For personal import of a prescription medicine that is not a controlled drug (eg, a CBD product) the importer must have a prescription from a New Zealand authorised prescriber (no more than 3 months supply of medicines).³⁷

³⁷ More information can be found at: <https://www.medsafe.govt.nz/consumers/miet/importmedicines.asp>

Part D: Distribution of products

201. Quality standards will be set for unapproved products supplied under the Scheme, including those products manufactured in New Zealand and imported. Products manufactured or imported under the Scheme will be assessed for compliance with the quality standards before being permitted for supply in New Zealand. This will require the manufacturer or importer to submit information to the Medicinal Cannabis Agency that demonstrates their product meets the quality standards that have been set under the Scheme.
202. We propose that if the Medicinal Cannabis Agency was satisfied that a product meets these quality standards, it would permit the supply of that product via a licence.
203. Unapproved medicinal cannabis products (including CBD products) can only be prescribed and supplied in New Zealand if they have been permitted for supply on a licence (either a Licence to Supply Unconsented Medicinal Cannabis Products under the Misuse of Drugs Act or a Licence to Sell Medicines by Wholesale under the Medicines Act).
204. All approved or provisionally approved medicinal cannabis products are required to be manufactured in accordance with Good Manufacturing Practice.
205. Unapproved products (supplied under section 29 of the Medicines Act) cannot be advertised. The Ministry of Health will provide a list of unapproved medicinal cannabis products that meet quality standards to medical practitioners (doctors).
206. The manufacturer or importer can also apply to the Ministry of Health for approval or provisional approval for distribution of their product in New Zealand. If approval or provisional approval were granted, the product could be advertised (noting that controlled drugs can only be advertised to medical professionals, dentists or pharmacists). Currently, the only medicinal cannabis product that has been granted approval is Sativex.[™]
207. Figures 2 and 3 below show the proposed supply chains for CBD and non-CBD products.

Figure 2: Proposed supply chain for CBD products

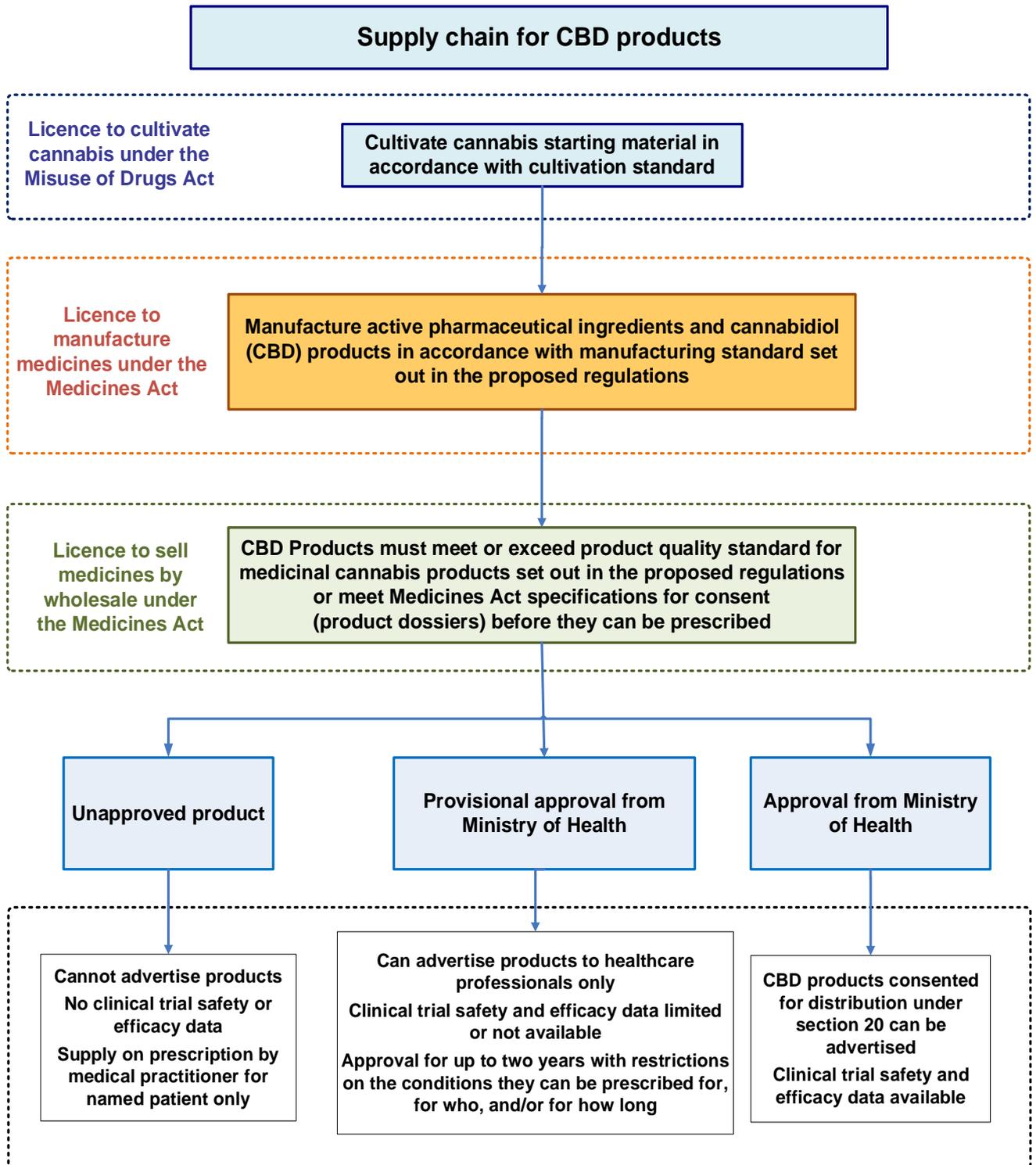
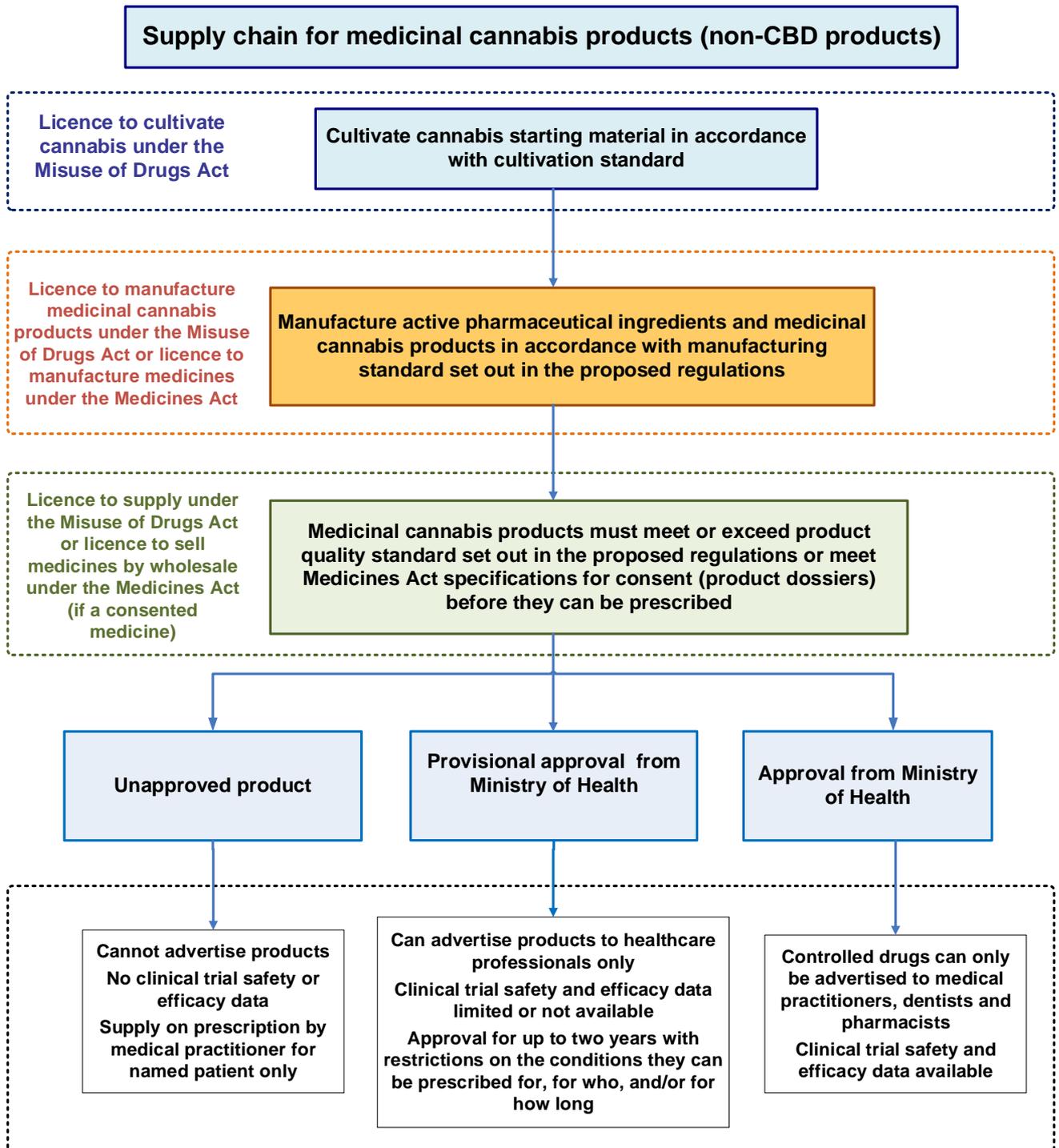


Figure 3: Proposed supply chain for medicinal cannabis products (non-CBD products)



D1: Distribution pathways

Approval for distribution of medicinal cannabis products

208. In most circumstances, medicine distributors need to obtain Ministry of Health approval to distribute before commencing distribution. Evidence to demonstrate that the product meets the claimed safety, efficacy (effectiveness) and quality standards for medicines is required. These are generally internationally agreed standards. The Ministry of Health reviews the evidence and, where the product is shown to meet these standards (or an alternative justified standard), approval can be granted.
209. The product can then be marketed as a medicine that has been manufactured to an acceptable standard of quality for the claims that are supported by the reviewed evidence. The medicine must be manufactured at a facility that complies with Good Manufacturing Practice and is licensed to manufacture medicines.

Provisional approval for distribution under section 23 of the Medicines Act

210. Provisional approval allows a product to be made available on a limited basis.
211. Provisional approval is ideally suited to medicines still undergoing clinical assessment, but where it is desirable that patients have early access. It is anticipated that the medicine would be used on a restricted basis until the risks and benefits have been quantified and full approval can be granted.
212. In exceptional circumstances, provisional approval may also be appropriate for medicines that will only be supplied in very limited circumstances for up to two years. The medicine distributor must still make an application and submit the safety, efficacy (effectiveness) and quality data available. The data is reviewed by the Ministry of Health, which may make recommendations on restricting the supply or the prescribing of the product as a condition of provisional approval. The medicine must still be manufactured at a facility that complies with Good Manufacturing Practice and is licensed to manufacture medicines.
213. When the provisional approval expires, the distributor can apply for a renewal, remove the medicine from the market or apply for full approval. It is expected that a distributor should generally submit an application for full approval within five years of provisional approval initially being granted.

Supply of unapproved products under section 29 of the Medicines Act

214. Section 29 of the Medicines Act permits the supply or sale of an unapproved medicine to medical practitioners (doctors), where they consider that it would benefit a named patient under their care. An application to supply is not required, and the Ministry of Health does not currently review the safety, efficacy (effectiveness) or the quality of the product. The medical practitioner is expected to exercise professional judgement (the professional and ethical standard of care) when authorising the supply of an unapproved product.
215. The supplier of the unapproved medicine must report (in writing) certain details of the supply to the Ministry of Health every month. These are the:
- name of the medicine supplied
 - dose form and strength
 - month and year of supply
 - place supplied to
 - number of packs sold or supplied
 - name of the practitioner and the patient
 - name and address of the supplier.

Section 25 of the Medicines Act 1981 allows for the medical practitioner to procure, administer and arrange the administration of an unapproved medicine. In effect, section 25 allows the medical practitioner (doctor) to enable the supply of the unapproved medicine through a pharmacy where the patient can fill the prescription in the same manner as their regular medications.

D1: Question for industry:

Do you have any comment on the proposal that a product can only be supplied under licence if it meets the requirements of the product quality standards?

Part E: Prescribing

E1: Prescribing requirements

Prescribing and distribution to patients

216. The prescribing requirements for medicinal cannabis products are intended to ensure appropriate levels of professional oversight are applied that reflect the risk of prescribing. Medicinal cannabis products can only be prescribed by a medical practitioner. When approved CBD products become available, these will also be able to be prescribed by a nurse practitioner. A 'medical practitioner', as used in this document, means all doctors registered by the Medical Council of New Zealand, including general practitioners and any other speciality.
217. All medicinal cannabis products except for CBD products are controlled drugs, which are more tightly controlled to manage risk.
218. Currently for medicinal cannabis products, except for CBD products, approval from a specialist working within a relevant scope of practice is required. For example, approval from a paediatrician or neurologist may be needed for medicinal cannabis products to treat complex epilepsy in a child. For some conditions treated by cannabis, such as epilepsy and nausea associated with chemotherapy, a specialist will often already be involved in the person's therapy.
219. The current paths for distributing prescription medicines and controlled drugs will continue to be used for medicinal cannabis products.
220. The prescribing requirements of medicinal cannabis products and CBD products fall into four categories:
- medicinal cannabis products that are controlled drugs approved by the Ministry of Health³⁸
 - unapproved medicinal cannabis products that are controlled drugs that meet the quality standards
 - unapproved medicinal cannabis products that are controlled drugs that do not meet the quality standards
 - CBD products.

³⁸ At this point in time, the only approved product is Sativex™.

E1: Question for prescribers and pharmacists:

Do you understand the current requirements for prescribing medicinal cannabis products?

E1: Questions for prescribers:

We are proposing that Ministry of Health approval to prescribe is not required for any medicinal cannabis products that meet the minimum quality standards.

Would you support another means of oversight in a prescribing decision, eg, peer review (a colleague to peer review a prescribing decision)? Do you have any suggestions for the oversight required?

E1: Questions for all:

Do you have any additional feedback on the proposals for prescribing medicinal cannabis products?

Medicinal cannabis products that are controlled drugs approved under section 20 of the Medicines Act

221. Currently a supporting recommendation from a specialist is required for on-label use if a medical practitioner (doctor) wishes to prescribe these products. On-label uses are the uses that have been approved by the Ministry of Health when approving the product for distribution in New Zealand. For off-label use, in addition to a recommendation or a prescription from a specialist, Ministry of Health approval to prescribe is needed.
222. We are seeking feedback on whether these requirements should be relaxed so that other medical practitioners (doctors) can prescribe independently for on-label use. Off-label use would still require a recommendation from a specialist, to ensure appropriate clinical oversight, but Ministry of Health approval to prescribe would not be required.

Table 4: Prescribing requirements – approved medicinal cannabis products that are controlled drugs

Current		Proposed	
On-label	Off-label	On-label	Off-label
<ul style="list-style-type: none"> • Specialist can prescribe or • Medical practitioner (doctor) can prescribe with a recommendation from a specialist 	<ul style="list-style-type: none"> • Specialist can prescribe with Ministry of Health approval or • Medical practitioner (doctor) can prescribe with a recommendation from a specialist and Ministry of Health approval 	<ul style="list-style-type: none"> • Specialist can prescribe or • Medical practitioner (doctor) can prescribe without recommendation from a specialist 	<ul style="list-style-type: none"> • Specialist can prescribe without Ministry of Health approval or • Medical practitioner (doctor) can prescribe with a recommendation from a specialist without Ministry of Health approval

E1: Questions for prescribers (on-label use of approved products)

What is your opinion on the proposal to remove the current requirement for a specialist recommendation for medical practitioners (doctors) to prescribe?

If you agree that the requirement for a specialist recommendation should be removed, should prescribing of medicinal cannabis products remain under the care of specialists in some circumstances (eg, prescribing medicinal cannabis products to children)?

Do you currently prescribe medicinal cannabis products that are controlled drugs for on-label use? **If yes, then how often?** Please explain why or why not.

If the requirement for a specialist recommendation were removed, would you still prescribe medicinal cannabis products that are controlled drugs for on-label use? Please explain why or why not.

E1: Questions for all (off-label use of approved products)

It is proposed that off-label use of approved medicinal cannabis products that are controlled drugs (eg, Sativex) can be prescribed by a medical practitioner with a specialist recommendation. Do you agree with this proposal? Please explain why or why not.

It is proposed that Ministry of Health approval to prescribe will not be required to prescribe approved medicinal cannabis products that are controlled drugs (eg, Sativex) for off-label use. Do you agree with this proposal? Please explain why or why not.

E1: Questions for prescribers (off-label use of approved products)

Do you currently prescribe approved medicinal cannabis products (eg, Sativex) that are controlled drugs for off-label use? If yes, then how often?

If the requirement for Ministry of Health approval to prescribe were removed, would you prescribe approved medicinal cannabis products (eg, Sativex) that are controlled drugs for off-label use? Please explain why or why not.

Unapproved medicinal cannabis products that are controlled drugs that meet the quality standards

223. Currently unapproved medicinal cannabis products that are controlled drugs, even if they are manufactured to the manufacturing quality standard, may only be prescribed by a specialist. We are seeking feedback on whether these products should be able to be prescribed by a medical practitioner (doctor) with the recommendation of a specialist or only be able to be prescribed by a specialist.

224. The reporting requirements of section 29 of the Medicines Act 1981 apply.

Table 5: Prescribing requirements – unapproved medicinal cannabis products that are controlled drugs that meet the quality standards

Current (unapproved but manufactured under GMP)	Proposed (unapproved but meeting the manufacturing and product quality standard)
Specialist can prescribe with Ministry of Health approval	<ul style="list-style-type: none">• Specialist can prescribe without Ministry of Health approval or• With specialist recommendation, a medical practitioner (doctor) can prescribe without Ministry of Health approval

E1: Question for all:

It is proposed that Ministry of Health approval will not be required to prescribe unapproved medicinal cannabis products that are controlled drugs that meet the quality standards. Do you agree with this proposal? Please explain why or why not

E1: Questions for prescribers:

Do you currently prescribe unapproved medicinal cannabis products that are controlled drugs that meet any standards of quality? If yes, then how often?

If the requirement for Ministry of Health approval to prescribe were removed, how likely are you to prescribe medicinal cannabis products that are controlled drugs that meet the proposed product quality standards? Please explain why.

Unapproved medicinal cannabis products that are controlled drugs that do not meet the quality standards

225. Unapproved medicinal cannabis products that are controlled drugs that do not meet the quality standards can currently only be prescribed by a specialist after obtaining approval from the Ministry of Health. It is proposed that the requirement for Ministry approval is continued to ensure the risk to the patient is minimised through an assessment of the proposed product and a review of the clinical proposal.
226. Once approval to prescribe a product has been granted, the product must be imported and supplied to that patient via a pharmacy or directly from their medical practitioner (doctor). The reporting requirements of section 29 of the Medicines Act 1981 apply.
227. Note that medicinal cannabis products manufactured in New Zealand and/or licensed for wholesale will have to meet the quality standards set under the Scheme. This means that any unapproved products that are controlled drugs that do not meet the quality standards will be imported to meet the needs of an identified patient under the care of a specialist. It is not expected that this pathway will be frequently used due to the increased availability of products meeting the quality standard under the Scheme.

Table 6: Prescribing requirements – unapproved medicinal cannabis products that are controlled drugs that do not meet the quality standards

Current	Proposed
Specialist can prescribe with Ministry of Health approval	No change

E1: Questions for prescribers:

Do you currently prescribe unapproved medicinal cannabis products that do not meet any quality standard? If yes, then how often?

Should Ministry of Health approval to prescribe continue to be required for unapproved medicinal cannabis products that do not meet the product quality standards?

E1: Question for all:

Do you agree with this proposal? Please explain why or why not

CBD products (approved or unapproved)

228. For unapproved CBD products a prescription from a medical practitioner (doctor) is required. Approved CBD products can be prescribed by a medical practitioner (doctor) or a nurse practitioner. This is because CBD products are no longer controlled drugs as a result of the enactment of the Misuse of Drugs (Medicinal Cannabis) Amendment Act 2018.
229. Note that all CBD products imported or manufactured in New Zealand will have to meet the manufacturing and product quality standards set under the Scheme. There may be some CBD products that do not meet the quality standards that will be allowed to be imported by a medical practitioner (doctor) to meet the needs of an identified patient under their care. It is not expected that this pathway will be frequently utilised due to the increased availability of CBD products meeting the quality standard under the Scheme.
230. The reporting requirements of section 29 of the Medicines Act 1981 apply if the CBD product is unapproved.

Table 7: Prescribing requirements – CBD products

Current	Proposed
Requires a prescription from a medical practitioner (doctor) if unapproved. If it is approved or provisionally approved, a nurse practitioner can also prescribe it	No change

E1: Questions for prescribers:

Do you currently prescribe CBD products? If yes, then how often?

No change is proposed to the prescribing arrangements for CBD products. Do you agree with this proposal?

E1: Question for all:

Do you agree with the proposal not to change the prescribing arrangements for CBD products? Please explain why or why not.

E2: Providing information to prescribers on products that meet the quality standards

231. Only a medical practitioner (doctor) can be supplied unapproved medicines under section 29 of the Medicines Act, so effectively only medical practitioners can prescribe them.
232. The Medicines Act states that no person shall advertise the availability of any unapproved medicines. Apart from Sativex™, all medicinal cannabis products currently available in New Zealand are unapproved.
233. However, the Misuse of Drugs Act allows information on controlled drugs to be distributed to medical practitioners (doctors) or contained in a publication that circulates solely or mainly to them. The Ministry of Health will make available a list of unapproved medicinal cannabis products that meet quality standards to medical practitioners.

E3: Providing information to prescribers on prescribing of medicinal cannabis products

234. In addition to information on prescribing requirements, medical practitioners may need information on:
 - the efficacy (effectiveness) of a particular product for a particular medical condition
 - the dose recommended for a particular condition (for example, recommended starting dose, maximum dose per day, time to onset of action, duration of action, dosage in children, people with renal impairment)
 - common adverse effects
 - drug interactions that they need to be aware of.
235. This information would only be available if the medicinal cannabis product has undergone reasonably comprehensive clinical trials. However, the majority of medicinal cannabis products supplied under the Scheme, at least initially, may be unapproved products.

236. It is proposed that the Medicinal Cannabis Scheme will not require clinical trials to be carried out for unapproved products. Because of this, medical practitioners (doctors) may be unwilling to prescribe medicinal cannabis products and it may also be difficult for them to pass on information and advice to patients on use, dosage and potential side effects. To assist medical practitioners in their decision to prescribe, manufacturers may wish to provide datasheets with their product, setting out what is known about it.

Prescribing requirements

237. The Ministry of Health will continue to use its website www.health.govt.nz to provide information to prescribers on the prescribing requirements (if any) for the various categories of medicinal cannabis products: for example, approved medicinal cannabis products, or unapproved medicinal cannabis products meeting the quality standard.

Information on the efficacy (effectiveness) and adverse effects of medicinal cannabis for patients

238. The Code of Health and Disability Services Consumers' Rights ('the Code') gives patients the right to be fully informed, make an informed choice and give informed consent. The Code requires written consent from the patient for experimental use of a medicine. The use of an unapproved medicine would be considered to be experimental if there is little documented support for the use, or the evidence is open to interpretation.³⁹ This highlights the need for information to be available to assist prescribers in making prescribing decisions and providing information to patients. This information needs to be readily accessible, clear, concise and up to date and to use best practice techniques in analysing research data (both individual clinical trials and meta-analyses).
239. Some jurisdictions (eg, Canada and Australia) have published information for health care professionals on the use of medicinal cannabis.⁴⁰ The Ministry of Health will provide guidance to medical practitioners (doctors) on resources that we have identified meet the criteria above. Professional organisations and some specialities have provided guidance to their members and are encouraged to continue to do so as new evidence becomes available.

³⁹ For more information on prescribing unapproved medicines, see <https://medsafe.govt.nz/profs/riss/unapp.asp>

⁴⁰ www.canada.ca/en/health-canada/services/drugs-medication/cannabis/information-medical-practitioners/information-health-care-professionals-cannabis-cannabinoids.html and www.tga.gov.au/medicinal-cannabis-guidance-documents

E3: Question for prescribers:

Do you have access to the information you need to prescribe medicinal cannabis products with confidence? If so, is it easy to understand?

E3: Questions for prescribers and pharmacists:

Please indicate your position on the following statements:

'I would be willing to prescribe or dispense unapproved medicinal cannabis products that are controlled drugs that have not undergone clinical trials.'

'I would be willing to prescribe or dispense unapproved CBD-products that have not undergone clinical trials.'

'I would be comfortable prescribing or dispensing unapproved medicinal cannabis products that are controlled drugs that have not undergone clinical trials.'

E3: Questions for patients / consumers:

Would you be comfortable taking medicinal cannabis products that have not been tested for safety and effectiveness? Please comment on whether this is true for certain types of products and not others.

Should specialist approval be required when being prescribed medicinal cannabis products?

Have you (or someone you know) been able to gain access to a specialist when required?

Part F: Post market controls

Controls for products after they go to market

240. The aim is to continually monitor and evaluate the safety and quality of medicinal cannabis products on the market and to manage any risks of harm associated with individual products. For approved products, the provisions of the Medicines Act 1981 and Medicines Regulations apply in full.
241. Some patients will likely be taking multiple medicines – for example, those suffering from chronic pain – and there is therefore a risk of interaction between different medicines. This risk must be well monitored to avoid harm. As with other medicines, this will include monitoring of effects by health professionals to identify potential interactions or adverse drug reactions and report any adverse effects to the Centre for Adverse Reactions Monitoring (CARM).
242. The Medicinal Cannabis Agency will regulate cannabis products throughout their lifecycle in many ways:
- licensing of cultivators, manufacturers, suppliers and researchers
 - controls on advertising
 - requiring product information for prescribers and consumers
 - monitoring compliance with licence conditions and quality standards
 - enforcing compliance with penalties such as suspending or cancelling a licence, and fines
 - monitoring adverse reaction reports for concerns in order to identify and evaluate adverse effects (pharmacovigilance)
 - amending product information, issuing safety alerts and recalls
 - sampling and testing for compliance with the quality standard and other requirements including labelling and prescriber and consumer information
 - collecting and assessing information about the products.
243. As the medicinal cannabis products under this Scheme are prescription medicines, some provisions of the Medicines Act apply even to unapproved products, and even if they are also controlled drugs. This includes the following obligations and requirements.

Duty to report untoward effects of products (medicines)

244. Under section 41 of the Medicines Act, an importer or manufacturer has a duty to report untoward effects of medicines, including of unapproved medicinal cannabis products that are distributed.

Investigation of quality issues and complaints and product recall

245. In order to be granted a manufacturing licence under the Medicines Act, manufacturers must have complaints and recall procedures in place. Similarly, manufacturers and suppliers proposing to manufacture or distribute unapproved medicinal cannabis products would be required to have complaints and recall procedures in place before they are granted a medicinal cannabis licence.
246. The enforcement provisions of Part 5 of the Medicines Act also apply to medicinal cannabis products. The Medicinal Cannabis Agency will have the ability to investigate any identified product quality issue and complaints.
247. If there are any issues with an unapproved medicinal cannabis product:
- licences issued under the Misuse of Drugs Act may be revoked (see below)
 - under section 37 of the Medicines Act, the Minister of Health may prohibit or impose conditions on a medicine's import, manufacture, packing, sale, possession, supply, administration or other use, for up to one year.
248. If there are any issues with an approved medicinal cannabis product:
- under section 35 of the Medicines Act, the Minister of Health may revoke or suspend an approval granted for a medicine on grounds of concern about its safety, efficacy (effectiveness) or quality
 - under section 36 of the Medicines Act, the Director-General of Health may require the manufacturer, importer or supplier to provide evidence about the safety or efficacy of a product, and the Ministry of Health may prohibit the supply of the product.
249. Under Regulation 50 of the Medicines Regulations 1984, the Director-General of Health may require an importer, manufacturer or seller to:
- withdraw from sale any medicine for which there is in force a notice under section 35 or section 37 of the Medicines Act, or
 - withdraw from sale any medicine, or any batch of a medicine, that does not meet the standards specified for it, or
 - dispose of any medicine or related product that has been directed to be withdrawn under regulation 50.
250. The importer, manufacturer or seller that receives an order under regulation 50 is required to advise the Director-General in writing of the manner and time in which it is proposed to comply with the order, and when the order has been complied with.
251. The Director-General may direct the recipient of an order under regulation 50 as to how it must be complied with.
252. The *New Zealand Medicines and Medical Devices Recall Code*⁴¹ includes procedures and processes as well as providing information on how the system for deciding on and executing recalls and similar market actions operates.

⁴¹ <https://medsafe.govt.nz/safety/recall-code-2015.asp>

253. Under section 39 of the Medicines Act, no person shall:
- add any substance to, or abstract (remove) any substance from, a medicine so as to affect injuriously (harmfully) the composition of the medicine, with intent that the medicine shall be sold or supplied in that state
 - sell or supply any medicine the composition of which has been injuriously (harmfully) affected by the addition or abstraction (removal) of any substance.
254. The regulator has the ability to test possible counterfeit (fake), adulterated or prosecution samples (those taken to support possible prosecution).⁴²
255. Under section 40 of the Medicines Act, CBD products will need to comply with the proposed product quality standards set by the regulator.

F: Questions for all:

As the medicinal cannabis products are medicines, some provisions of the Medicines Act will apply.

Please indicate your position on the following proposal:

‘The current post market monitoring and compliance requirements for medicines should be applied to all medicinal cannabis products.’

Do you have any additional comments on the proposed approach to post market monitoring and compliance?

Proposed enforcement powers

256. The Medicinal Cannabis Agency will have the ability to vary, suspend or revoke licences, where licence conditions are not met, or on the grounds of concern about product safety or quality.
257. The Medicinal Cannabis Agency will also have the ability to impose penalties for non-compliance with relevant product quality standards, with relevant product information requirements or with licence conditions.
258. Under the Misuse of Drugs Act, the Medicinal Cannabis Agency will be able to order the seizure and destruction of products being manufactured or distributed without the relevant licence.

F: Question for all:

Do you have any comments on the proposed enforcement powers?

⁴² An adulterated sample is one that has had ingredients without medicinal effects added but not disclosed.

Proposed information collection

259. In order to determine whether the objectives of the Scheme are being met, the Medicinal Cannabis Agency will collect data about the amount of medicinal cannabis being supplied. There will also be ongoing monitoring and regular evaluation of the Medicinal Cannabis Scheme to assess progress against its objectives, as well as to identify any barriers to access, gaps in understanding and other issues.
260. The Medicinal Cannabis Agency will also survey medical practitioners (doctors) and nurse practitioners about their confidence and willingness in prescribing products, the conditions that the products are being used to treat, and their effectiveness in use. This will also include specific engagement with organisations with a focus on Māori health needs.

F: Question for all:

In your opinion, what is the key information the agency needs to collect to monitor progress against the objectives of the Scheme?

Part G: Cost recovery and proposed fees and charges

Cost recovery

261. Cost recovery specifically applies to services that the government has a statutory (legal) authority to deliver. Fees can be charged for a service directly provided to (or directly benefiting) individuals or organisations.
262. In setting these proposed fees, the Ministry of Health has taken into consideration the principles outlined in the New Zealand Treasury *Guidelines for Setting Charges in the Public Sector (2017)*. These guidelines recommend full recovery of the direct costs associated with the specific licensed activities. Feedback from the consultation will be used to inform final decisions to be made by Cabinet on the proposed cost recovery regime for the Medicinal Cannabis Scheme, which will be set out in regulations to be made in December 2019.
263. The proposed fees are calculated based on full recovery of the direct costs associated with the specific licensed activities, as recommended by the Treasury Guidelines.
264. All licence fees will be payable when an application is submitted. No work on the application will commence until the Medicinal Cannabis Agency has received full payment of the fee.
265. In situations where an applicant requires multiple licences, a reduction in fees may apply. This potential reduction applies if the Medicinal Cannabis Agency is reasonably satisfied that the information and documents provided for each application are sufficiently similar to reduce the work involved in assessing them.

Medicinal cannabis licence fees – overview

266. The Misuse of Drugs Act 1975 provides the ability for the Medicinal Cannabis Agency to make regulations to prescribe fees payable for licences, allowing for the costs of assessing and issuing a licence and the costs of administering the monitoring regime to be recovered from users. The proposed licensing regime for the Medicinal Cannabis Scheme will include fees for the following activities:
 - cultivation of cannabis plant material, with a separate fee for considering declarations of illicit seed grown in New Zealand
 - manufacture of medicinal cannabis products (includes the manufacture of active pharmaceutical ingredients and the packaging of products)

- supply of medicinal cannabis products, with a separate fee to cover assessing products to verify that they meet the quality standards and to authorise their supply.
267. The proposed fee for each licence is based on the direct time and costs involved with:
- receipt of applications, and screening of applications to determine completeness of the information provided
 - assessment of application and police vetting of applicants
 - on-site audits related to the application
 - monitoring that the licence holder is complying with the licence conditions.
268. Indirect costs such as those for establishing the Medicinal Cannabis Scheme, policy development and enforcement activities are not included in the calculating of the proposed fees.

Notes on proposed fees for Licence to Cultivate Medicinal Cannabis

269. The Licence to Cultivate includes ongoing monitoring of compliance with licence conditions.
270. Fees for a declaration of illicit seed will be additional to the fees for a Licence to Cultivate. This is a one-off fee for each declaration of illicit seed that can only be made by a licensed cultivator or an applicant for a cultivation licence.
271. We expect that the number of declarations of illicit seed will be high initially and decrease when a licit (legal) supply chain has been established for New Zealand seeds.

Notes on proposed fees for Licence to Manufacture

272. If GMP is used as a manufacturing standard, then a Licence to Manufacture Medicines will be issued under the Medicines Act and the existing schedule of fees under the Medicines Act will apply.
273. The fee for a Licence to Manufacture Medicines is currently \$13,750 (including GST). For sites that only pack medicines, there is a separate licence fee for a Licence to Pack Medicines (\$845 including GST). A Misuse of Drugs licence is also needed for medicinal cannabis products that are also controlled drugs.
274. If GPP is used as a manufacturing standard, then licences to manufacture under GPP would be issued under the Misuse of Drugs Act 1975.

Notes on proposed fees for Licence to Supply Unconsented Medicinal Cannabis Products

275. Medicinal cannabis products will not be able to be sold under the Medicinal Cannabis Scheme unless they have been assessed by the Medicinal Cannabis Agency and authorised through the Licence to Supply Unconsented Medicinal Cannabis Products.
276. Verification that a product meets the quality standards (a product assessment) will be required for each product, with each product assessment attracting a one-off fee per product. If, for example, a supplier intends to supply six products, the fee payable is six times the product assessment fee in addition to the fee for obtaining a Licence to Supply Unconsented Medicinal Cannabis Products (or a Licence to Sell Medicines by Wholesale).
277. A product assessment is specific to each supplier. If two separate suppliers wish to supply the same product, they must both have the product assessed for verification that it meets the quality standard.
278. In addition to the activities listed above, a Licence to Supply Unconsented Medicinal Cannabis Products includes the cost of pharmacovigilance activities as these are directly related to the product being supplied.⁴³ This will involve the monitoring of the medicinal cannabis products available under the Scheme, including adverse effect reporting and product recalls.

Notes on proposed fees for licences to import and export controlled drugs

279. The current fee for a Licence to Import Controlled Drugs or a Licence to Export Controlled Drugs is specified in the schedule to the Misuse of Drugs Regulations) as \$194.22 (including GST). These fees are currently not proposed to change under the Scheme.

Notes on proposed fees – comparing GMP and GPP

280. The proposed fees have been calculated based on full recovery of the direct costs associated with the specific licensed activities. Table 8 reflects the assumption that the number of annual licence holders and renewals will stabilise after four years as the industry matures.
281. This calculation includes the assumption that not all applications will be approved, and every year 20 percent of licences will not be renewed. However, given this is a new industry, the Ministry of Health is unable to predict the volume or demand for licence applications with a high degree of certainty and will monitor the fees on an ongoing basis. The fees may need to be adjusted to reflect changes in regulatory costs and industry and regulatory developments.

⁴³ Pharmacovigilance activities are the practice of monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported adverse reactions.

Table 8: Proposed licence fees

Type of licence	New licence application or renewal	Estimated licence volumes	All licences to manufacture are under GMP	Half of the licences to manufacture are under GMP and half are under GPP	
				Fees for GMP	Fees for GPP
Cultivate 1 – Small	New application	6	\$16,800	\$14,200	\$14,200
	Renewal	2	\$13,200	\$11,100	\$11,100
Cultivate 2 – Large	New application	10	\$23,200	\$19,500	\$19,500
	Renewal	3	\$16,800	\$14,200	\$14,200
Cultivate – Declaration	N/A	20	\$1,500	\$1,200	\$1,200
Packing medicines	New application	3	\$1,811 ¹	\$1,811 ¹	\$22,600
	Renewal	2	\$1,811 ¹	\$1,811 ¹	\$14,200
Manufacture medicines	New application	3	\$14,716 ¹	\$14,716 ¹	\$32,500
	Renewal	1	\$14,716 ¹	\$14,716 ¹	\$20,800
Supply – Full	New application	10	\$21,100	\$17,800	\$17,800
	Renewal	3	\$17,400	\$14,700	\$14,700
Product assessment	N/A	10	\$21,100	\$13,900	\$13,900
Licence to import	Per consignment	–	\$194.22 ²	\$194.22 ²	\$194.22 ²
Licence to export	Per consignment	–	\$194.22 ²	\$194.22 ²	\$194.22 ²

1. These are the existing fees for a Licence to Manufacture under the Medicines Act combined with the fees for a controlled drug licence (CBD products will only need a Licence to Manufacture under the Medicines Act).
2. These are existing fees for import and export licences under the Misuse of Drugs Act.

282. The current fees for packing medicines and manufacturing medicines under GMP have already been set under the Medicines Act and the Misuse of Drugs Act and so are not being consulted on. These current fees have been set at a level that does not reflect full cost recovery. However, these fees may be reviewed in the near future. Consultation closed in April 2019 on the proposed Therapeutic Products Bill, which would replace the Medicines Act 1981 and would establish a new regulatory scheme for therapeutic products, including medicines. This proposed new regulatory scheme would include a fees review that would be informed by the latest Treasury Guidelines on cost recovery.

283. We are seeking feedback on the options for a manufacturing standard. The fees in the above table are based on two options: (1) the adoption of GMP as the manufacturing standard for all medicinal cannabis products; or (2) GMP as per (1) with GPP also allowed for some dose forms. The fees for this second option have been calculated on the assumption that half of the Licences to Manufacture will be issued under the Medicines Act (GMP) and half under the Misuse of Drugs Act (GPP).

G: Question for researchers:

Will the proposed fees affect your ability to research medicinal cannabis products or cannabis?

G: Questions for industry:

Based on the proposed fees, how likely are you to enter the medicinal cannabis market?

Which licence(s) do you intend to apply for within the next two years?

G: Questions for all:

What is your view of the following statement:

'The fee structure and approach are fair for both licence holders and the public.'

Do you have any additional comments on the proposed approach to fees?

Part H: Proposals and consultation questions

Submitters are asked to provide the following information:

This submission was completed by: _____ (name)

Address: _____ (street/box number)

_____ (town/city)

Email: _____

Organisation (if applicable): _____

Position/Profession (if applicable/relevant): _____

Are you submitting this *(tick one box only in this section)*:

- as an individual or individuals (not on behalf of an organisation)
- on behalf of a group or organisation(s)

Please do not include information that identifies people breaking the law. If you are an individual or individuals and you check the following box, the Ministry of Health will remove your personal details from your submission, and your name(s) will not be listed in the published summary of submissions.

- I do not give permission for my personal details to be released.

The above information will be taken into consideration if your submission is requested under the Official Information Act 1982 (OIA). People in New Zealand can request information from government and government agencies under the OIA. This information will be made available unless there is a good reason to withhold it. The OIA is important for ensuring government is open and transparent.

If you are an individual or individuals, please indicate which group you identify with / your submission represents *(you may tick more than one box in this section)*:

- | | |
|---|--|
| <input type="checkbox"/> Consumer/Patient | <input type="checkbox"/> Māori |
| <input type="checkbox"/> Medical practitioner (doctor) | <input type="checkbox"/> Pacific |
| <input type="checkbox"/> Nurse practitioner | <input type="checkbox"/> Asian |
| <input type="checkbox"/> Pharmacist | <input type="checkbox"/> Pākehā/European |
| <input type="checkbox"/> Medical – other | |
| <input type="checkbox"/> Researcher/Academic | <input type="checkbox"/> Other – <i>(please specify)</i> : |
| <input type="checkbox"/> Industry <i>(please specify)</i> : | |

If you are an organisation, please indicate which group you identify with / your submission represents (*you may tick more than one box in this section*):

- | | |
|--|---|
| <input type="checkbox"/> Consumer/patient group | <input type="checkbox"/> Local government |
| <input type="checkbox"/> Medical professional association | <input type="checkbox"/> Industry: hemp |
| <input type="checkbox"/> Pharmacy professional association | <input type="checkbox"/> Industry: medicinal cannabis cultivate |
| <input type="checkbox"/> Nurse professional association | <input type="checkbox"/> Industry: medicinal cannabis manufacture |
| <input type="checkbox"/> Other professional association | <input type="checkbox"/> Industry: medicinal cannabis supply |
| <input type="checkbox"/> Non-governmental organisation | <input type="checkbox"/> Industry: Māori |
| <input type="checkbox"/> Academia/Research institute | <input type="checkbox"/> Māori: other group |
| <input type="checkbox"/> District health board | |
| <input type="checkbox"/> Central government | <input type="checkbox"/> Other (<i>please specify</i>): |

Table of proposals and consultation questions

Document part	Proposals and questions
Overall	<p>In this table, we note the audience(s) we think the proposal and/or question is most relevant for. For example, much of Part E: Prescribing has questions for prescribers, though some of these may also be of interest to consumers, industry or other groups. We encourage you to answer or provide comments on any proposals or questions you feel are relevant. Questions are coloured by audience: all, industry, patients/consumers, pharmacists, prescribers, researchers.</p>
Overall	<p>Question for all:</p> <ul style="list-style-type: none"> Please provide here any overall comments on the proposals in the consultation document.
Overall	<p>Question for all:</p> <ul style="list-style-type: none"> Do you think the current proposals and options in this document would meet the Government’s objective of improving patient access to quality, affordable medicinal cannabis products? Please explain why/why not.
A4	<p>Equity</p> <p>There should be equity of access to the economic benefits of a medicinal cannabis industry. It is important that the Medicinal Cannabis Agency has the capacity and capability to support iwi and other Māori groups to understand the medicinal cannabis requirements for industry.</p> <p>Question for all:</p> <ul style="list-style-type: none"> What do you think is the best way to achieve equity of access to the economic benefits of a medicinal cannabis industry? <p>Question for all:</p> <p>Have you (or someone you know) had difficulty in accessing medicinal cannabis products (eg, due to cost, availability of products, patient–prescriber relationship, information on products available)? If yes, please provide comments as to why.</p> <p>Questions for prescribers:</p> <ul style="list-style-type: none"> As a prescriber, what do you see as the barriers to patient access to medicinal cannabis products? Please indicate your position on the following statement: ‘There are greater barriers to accessing medicinal cannabis products for particular patients.’ If you agree, please discuss the barriers.

Document part	Proposals and questions
B2	<p><u>PROPOSAL</u></p> <p>Proposed quality standards for cultivation:</p> <p>There are three proposed options for a quality standard for cultivation:</p> <p>A. Manufacturer sets a process or a starting material product standard.</p> <p>B. Regulator sets a cultivation process standard.</p> <p>C. Regulator sets quality standard for starting material.</p> <p>Questions for industry and researchers:</p> <ul style="list-style-type: none"> • Do you or your organisation currently hold a licence to cultivate cannabis for medicinal or scientific research purposes? • How likely are you to apply for a licence to commercially cultivate cannabis for medicinal purposes? • Which option for cultivation standards do you prefer? <ul style="list-style-type: none"> A. <i>Manufacturer sets a process or a starting material product standard.</i> B. <i>Regulator sets a cultivation process standard.</i> C. <i>Regulator sets quality standard for starting material.</i> • In your view, what are the advantages and disadvantages of each of the options? • If you prefer option B (Regulator sets a cultivation process standard), which of the following cultivation process standards would be your preference? • How likely are you to apply for a licence to commercially cultivate cannabis for medicinal purposes if option A (Manufacturer sets a process or a starting material product standard) was the preferred option? • How likely are you to apply for a licence to commercially cultivate cannabis for medicinal purposes if option B (Regulator sets a cultivation process standard) was the preferred option? • How likely are you to apply for a licence to commercially cultivate cannabis for medicinal purposes if option C (Regulator sets quality standard for starting material) was the preferred option? • How many cultivation sites are you planning? • What would be the average size of each cultivation area? • Do you have any additional comments on the proposed options for cultivation standards?

Document part	Proposals and questions
B3	<p><u>PROPOSAL:</u></p> <p>Proposed quality standards for manufacturing</p> <p>There are two options for a manufacturing process quality standard.</p> <ul style="list-style-type: none"> A. Adopt the current New Zealand approach for manufacturing in accordance with Good Manufacturing Practice (GMP) (Medicines Act) for all medicinal cannabis products. B. Allow for the manufacture of some medicinal cannabis product dose forms under GMP (Medicines Act) and some medicinal cannabis dose forms under Good Production Practices (GPP) (Misuse of Drugs Act). <p>Questions for all:</p> <ul style="list-style-type: none"> • What is your preferred manufacturing standard for medicinal cannabis products in New Zealand? • If you prefer allowing GPP for some prescription medicines, which dose forms of medicinal cannabis products should be allowed to be manufactured to GPP? • Please indicate your position on the following statements: ‘New Zealand should only allow GMP as the manufacturing standard for medicinal cannabis products’. ‘New Zealand should allow GPP as the manufacturing standard for some forms of medicinal cannabis products (eg, dried cannabis and cannabis oils). • Do you think medicinal cannabis products should be manufactured to the same standard with regard to consistency and quality as other medicines? • Do you have any additional comments on the proposed options for manufacturing medicinal cannabis products? • We are seeking information that compares the cost to the public of the same product under GPP and under GMP. Do you have any information you can share on potential or actual product costs under either option? <p>Questions for industry:</p> <ul style="list-style-type: none"> • Do you currently hold a Licence to Manufacture Medicines? • How likely are you to apply for a Licence to Manufacture Medicinal Cannabis Products? • How likely are you to apply for a Licence to Manufacture Medicinal Cannabis Products if the preferred manufacturing standard for all medicinal cannabis products is Good Manufacturing Practice (GMP)? • How likely are you to apply for a Licence to Manufacture Medicinal Cannabis Products under Good Production Practice, GPP, if it is an option for some dose forms (for example, dried cannabis, and cannabis oils)?

Document part	Proposals and questions
	<ul style="list-style-type: none"> • What types of medicinal cannabis products do you intend to manufacture? • If you are intending to manufacture medicinal cannabis products to GMP, in what timeframe (from the start of the Medicinal Cannabis Scheme) do you think you will have products available for assessment for supply? • If you are intending to manufacture medicinal cannabis products to GPP, in what timeframe (from the start of the Medicinal Cannabis Scheme) do you think you will have products available for assessment for supply? • We are seeking information that compares the cost to the public of the same product under GPP and under GMP. Do you have any information you can share on potential or actual product costs under either option? <p>Questions for prescribers:</p> <ul style="list-style-type: none"> • How likely are you to prescribe a medicinal cannabis product that has been manufactured to GMP? • How likely are you to prescribe a medicinal cannabis product that has been manufactured to GPP?
B4	<p><u>PROPOSAL:</u></p> <p>Proposed quality standards for active pharmaceutical ingredients</p> <p>The proposed quality standard for active pharmaceutical ingredients (APIs) is the product specifications set out in the New Zealand Product Quality Standards Monograph (see Appendix 2).</p> <p>Question for industry:</p> <ul style="list-style-type: none"> • If you are manufacturing API, how likely are you to apply for a licence to manufacture them if API are required to meet quality standards? <p>Questions for all:</p> <ul style="list-style-type: none"> • What is your opinion of the following proposal: All active pharmaceutical ingredients (API) should be required to meet the requirements of the New Zealand Product Quality Standards Monograph. • Do you have any additional comments on the proposed option for the API product quality standard?

Document part	Proposals and questions
B4	<p><u>PROPOSAL:</u></p> <p>Finished product quality standard – dose form requirements</p> <p>Medicinal cannabis products that are intended to be smoked, and food containing medicinal cannabis, will not be allowed under the Medicinal Cannabis Scheme.</p> <p>It is proposed that the following dose forms would only be allowed if they are approved or provisionally approved under the Medicines Act:</p> <ul style="list-style-type: none"> • modified-release dose forms • sterile dose forms (injectables, and eye and ear preparations). <p>Question for all:</p> <ul style="list-style-type: none"> • Please indicate your position on the following statement: 'It is proposed that the finished product quality standard should include the dose form requirements.' • Should there be a limit on the amount of active pharmaceutical ingredient in each dose? If yes, what do you think the limit per dose should be? • Do you have any additional comments on the proposed dose form requirements? <p>Questions for prescribers:</p> <ul style="list-style-type: none"> • What types of products would you be most likely to prescribe? • If you were to prescribe medicinal cannabis products, which route of delivering the medicine would you be most likely to prescribe?
B4	<p><u>PROPOSAL:</u></p> <p>Finished product quality standard – product specification</p> <p>The proposed finished product quality standard includes the product specifications set out in the New Zealand Product Quality Standards Monograph (see Appendix 2), plus dose form requirements, stability and shelf life requirements, packaging and labelling requirements, and quality requirements for excipients.</p> <p>Questions for industry:</p> <ul style="list-style-type: none"> • How likely are you to apply for a licence to manufacture based on the requirements of the proposed quality standard for finished products? • What is your opinion of the proposal that the finished product quality standard should include the above requirements?

Document part	Proposals and questions
B4	<p><u>PROPOSAL:</u></p> <p>Testing to meet the product quality standards</p> <p>It is proposed that each batch of API and finished product will be required to be tested and that evidence is provided to the regulator to verify that the product meets the quality standards.</p> <p>The evidence required would be Certificates of Analysis, which certifies that the product meets the required product specifications and gives additional evidence supporting compliance with stability, shelf life, packaging and labelling, excipient and dose form requirements.</p> <p>Questions for industry:</p> <ul style="list-style-type: none"> • Please indicate your position on the following proposal: 'Batch testing should be required to provide evidence that the product meets the requirements of the product quality standard.' • Do you have any additional comments on the proposed testing requirements?
C3	<p><u>PROPOSAL:</u></p> <p>Licensing under the Scheme</p> <p>It is proposed that the general licensing requirements listed in Section C3 must be met for all licence applications.</p> <p>Questions for industry:</p> <ul style="list-style-type: none"> • Are any of the proposed licensing requirements likely to impact on your ability to apply for a licence? If yes, please provide details. • Do the proposed licensing requirements create equity issues about who is able to enter the sector? For example, are there any barriers to obtaining a licence to cultivate for growing on Māori land?
C4	<p><u>PROPOSAL:</u></p> <p>Licence to Cultivate</p> <p>It is proposed that the licensing requirements listed in part C4 must be met in addition to the general licensing requirements in part C3.</p> <p>Questions for industry and researchers:</p> <ul style="list-style-type: none"> • Are any of the proposed licensing requirements likely to impact on your ability to apply for a licence to cultivate? If yes, please provide details.

Document part	Proposals and questions
	<ul style="list-style-type: none"> • What are your views on the proposal to allow growers of industrial hemp to be able to supply seeds to medicinal cannabis licensees and industrial hemp licensees? Please explain. • What are your views on the proposal to allow medicinal cannabis licensees to be able to supply seeds to industrial hemp licensees? Please explain <p><u>PROPOSAL:</u></p> <p>It is proposed that there are two types of licences – one for ‘small scale’ (cultivation area less than 200 m²) and one for ‘large scale’ (cultivation area greater than 200 m²).</p> <p>Question for industry and researchers:</p> <ul style="list-style-type: none"> • Is the proposed 200 m² cultivation area an appropriate cut-off level between small-scale and large-scale cultivation? Please provide comment.
C5	<p><u>PROPOSAL:</u></p> <p>We are proposing that a licence holder will be able to use local varieties of cannabis for cultivation. To do this, the licence holder will need to make a declaration to allow them to use the seeds to be legally grown in New Zealand.</p> <p>Question for all:</p> <ul style="list-style-type: none"> • Should there be limits on the amount of seed or the number of declarations that could be allowed? Please provide an explanation for your view.
C6	<p><u>PROPOSAL:</u></p> <p>Transition from research to commercial:</p> <p>We propose to allow a small number of plants to be transferred from a licence to cultivate cannabis for scientific and medical research to a licence to cultivate cannabis for commercial purposes.</p> <p>Question for industry and researchers:</p> <ul style="list-style-type: none"> • What would be the minimum number of plants you require to retain in order to maintain specific cultivars, when moving from a research to a commercial cultivation operation? Please provide justification for numbers suggested.

Document part	Proposals and questions
C7	<p><u>PROPOSAL:</u></p> <p>Licence to Manufacture</p> <p>It is proposed that the licensing requirements listed in Section C7 must be met in addition to the general licensing requirements in Section C3.</p> <p>Question for industry:</p> <ul style="list-style-type: none"> • Are any of the proposed licensing requirements likely to impact on your ability to apply for a licence to manufacture? If yes, please provide details.
C8	<p><u>PROPOSAL:</u></p> <p>Licence to Sell Medicines by Wholesale</p> <p>A Licence to Sell Medicines by Wholesale issued under the Medicines Act is required for distribution of CBD products by wholesale. It is proposed that any CBD products supplied must, as a minimum, meet the finished product quality standard, which includes the New Zealand Product Quality Standards Monograph and requirements for dose form, packaging and labelling, stability and shelf life, and excipients. Evidence must be provided to the regulator that verifies that the products meet the finished product quality standard.</p> <p>Question for industry:</p> <ul style="list-style-type: none"> • How likely is this proposed requirement to impact on your ability to apply for a licence to sell medicines (CBD products) by wholesale? Please explain.
C9	<p><u>PROPOSAL:</u></p> <p>Licence to Supply Unconsented Medicinal Cannabis Products under Misuse of Drugs Act</p> <p>It is proposed that products, as a minimum, must meet the finished product quality standard, which includes the New Zealand Product Quality Standards Monograph and requirements for dose form, packaging and labelling, stability and shelf life, and excipients. Evidence must be provided to the regulator that verifies that the products meet the finished product quality standard before they can be supplied.</p> <p>It is further proposed that these requirements would apply to both imported and locally manufactured products.</p> <p>Questions for industry:</p> <ul style="list-style-type: none"> • How likely are these requirements to impact on your ability to apply for a Licence to Supply Unconsented Medicinal Cannabis Products under the Misuse of Drugs Act? If yes, please explain why. • Do you have any additional comments on the proposed options for supplying medicinal cannabis products?

Document part	Proposals and questions
C12	<p><u>PROPOSAL:</u></p> <p>Import</p> <p>All imported or exported products must, as a minimum, meet the New Zealand product quality standards.</p> <p>Questions for industry:</p> <ul style="list-style-type: none"> • Based on the proposals outlined in Section C12, how likely are you to import medicinal cannabis products? • How likely are these requirements to impact on your ability to apply for a Licence to Supply Unconsented Medicinal Cannabis Products under the Misuse of Drugs Act? Please explain. <p>Question for all:</p> <ul style="list-style-type: none"> • What forms of medicinal cannabis products are you interested in importing?
C12	<p><u>PROPOSAL:</u></p> <p>Export:</p> <p>(a) In order to continue to meet our international obligations under the Single Convention on Narcotic Drugs 1961 and to minimise the risk of diversion, we are proposing to not allow for the export of unprocessed or bulk raw cannabis. This restriction does not apply to final dose form, standardised, packaged and labelled raw cannabis that meets the New Zealand product quality standards and that can be exported into medicinal markets overseas under the conditions of an export licence.</p> <p>(b) All imported or exported products must, as a minimum, meet the New Zealand product quality standards.</p> <p>Questions for industry:</p> <ul style="list-style-type: none"> • How likely are you to export medicinal cannabis products based on the above proposals? • If allowed, what type of medicinal cannabis product would you be interested in exporting? • What finished dose forms of medicinal cannabis products are you interested in exporting? <p>Question for all:</p> <ul style="list-style-type: none"> • Should the export of unprocessed or bulk raw cannabis be allowed? Please explain why/why not.

Document part	Proposals and questions
D	<p><u>PROPOSAL:</u></p> <p>Distribution</p> <p>We propose that if the Medicinal Cannabis Agency was satisfied that a product meets the Scheme’s quality standards, it would allow the supply of that product via a licence.</p> <p>Question for industry:</p> <ul style="list-style-type: none"> Do you have any comment on the proposal that a product can only be supplied under licence if it meets the requirements of the product quality standards?
E1	<p><u>PROPOSAL:</u></p> <p>That Ministry of Health approval to prescribe is not required for any medicinal cannabis products that meet the minimum quality standards.</p> <p>Questions for prescribers:</p> <ul style="list-style-type: none"> Would you support another means of oversight in a prescribing decision, eg, peer review (a colleague to peer review a prescribing decision)? Do you have any suggestions for the oversight required? <p>Question for prescribers and pharmacists:</p> <ul style="list-style-type: none"> Do you understand the current requirements for prescribing medicinal cannabis products? <p>Question for all:</p> <ul style="list-style-type: none"> Do you have any additional feedback on the proposals for prescribing medicinal cannabis products? <p><u>PROPOSAL: (on-label use of approved products)</u></p> <p>This proposal is for the uses of the product approved by the Ministry of Health (known as “on-label” uses). It is proposed that approved medicinal cannabis products that are controlled drugs can be prescribed by medical practitioners (doctors) without the need for a recommendation from a specialist for “on-label” (approved) uses.</p>

Document part	Proposals and questions
	<p>Questions for prescribers:</p> <ul style="list-style-type: none"> • What is your opinion on the proposal to remove the current requirement for a specialist recommendation for medical practitioners (doctors) to prescribe? • If you agree that the requirement for a specialist recommendation should be removed, should prescribing of medicinal cannabis products remain under the care of specialists in some circumstances (eg, prescribing medicinal cannabis products to children)? • Do you currently prescribe medicinal cannabis products that are controlled drugs for on-label use? Please explain why or why not. If yes, then how often? • If the requirement for a specialist recommendation were removed, would you prescribe medicinal cannabis products that are controlled drugs for on-label use? Please explain why or why not. <p><u>PROPOSAL:</u></p> <p>This proposal is for the unapproved uses of a medicinal cannabis product (known as “off-label” uses). It is proposed that approved medicinal cannabis products that are controlled drugs can be prescribed by a specialist, or by a medical practitioner (doctor) with a specialist recommendation for these “off-label” uses, without the need for Ministry approval to prescribe.</p> <p>Questions for all:</p> <ul style="list-style-type: none"> • It is proposed that off-label use of approved medicinal cannabis products that are controlled drugs (eg, Sativex) can be prescribed by a medical practitioner with a specialist recommendation. Do you agree with this proposal? Please explain why or why not. • It is proposed that Ministry of Health approval to prescribe will not be required to prescribe approved medicinal cannabis products that are controlled drugs (eg, Sativex) for off-label use. Do you agree with this proposal? Please explain why or why not. <p>Questions for prescribers:</p> <ul style="list-style-type: none"> • Do you currently prescribe approved medicinal cannabis products (eg, Sativex) that are controlled drugs for off-label use? If yes, then how often? <p>If the requirement for Ministry of Health approval to prescribe were removed, would you prescribe approved medicinal cannabis products (eg, Sativex) that are controlled drugs for off-label use? Please explain why or why not.</p>

Document part	Proposals and questions
	<p><u>PROPOSAL:</u></p> <p>It is proposed that Ministry of Health approval to prescribe will not be required for unapproved medicinal cannabis products that are controlled drugs that meet the quality standards.</p> <p>Question for all:</p> <ul style="list-style-type: none"> • Do you agree with this proposal? Please explain why or why not. <p>Questions for prescribers:</p> <ul style="list-style-type: none"> • Do you currently prescribe unapproved medicinal cannabis products that are controlled drugs that meet any standards of quality? If yes, then how often? • If the requirement for Ministry of Health approval to prescribe were removed, how likely are you to prescribe medicinal cannabis products that are controlled drugs meeting the proposed product quality standard? Please explain why. <p><u>PROPOSAL:</u></p> <p>No change is proposed for unapproved medicinal cannabis products that are controlled drugs that do not meet the quality standards. We propose these products can only be prescribed by a specialist and that Ministry of Health approval to prescribe is still required.</p> <p>Questions for prescribers:</p> <ul style="list-style-type: none"> • Do you currently prescribe unapproved medicinal cannabis products that do not meet any standards of quality? If yes, then how often? • Should Ministry of Health approval to prescribe unapproved medicinal cannabis products that do not meet the product quality standards continue to be required? <p>Question for all:</p> <ul style="list-style-type: none"> • Do you agree with this proposal? Please explain why or why not. <p><u>PROPOSAL:</u></p> <p>No change is proposed for CBD products. These will still require a prescription from a medical practitioner if they are unapproved. A nurse practitioner can also prescribe them if they are approved or provisionally approved.</p>

Document part	Proposals and questions
	<p>Questions for prescribers:</p> <ul style="list-style-type: none"> • Do you currently prescribe CBD products? If yes, then how often? • No change is proposed to the prescribing arrangements for CBD products. Do you agree with this proposal? <p>Question for all:</p> <p>What are your views on the proposal not to change the prescribing arrangements for CBD products? Please explain</p>
E3	<p><u>PROPOSAL:</u></p> <p>Provision of information to prescribers on prescribing of medicinal cannabis products.</p> <p>The Medicinal Cannabis Scheme is proposing to not require clinical trials to be carried out for unapproved medicinal cannabis products (approved or provisionally approved medicinal cannabis products would require clinical trial data).</p> <p>Question for all:</p> <ul style="list-style-type: none"> • Would you expect an unapproved medicinal cannabis product to have undergone the same clinical trials as for an approved medicine? Please explain why or why not. <p>Questions for prescribers and pharmacists:</p> <p><u>Please indicate your position on the following statements:</u></p> <ul style="list-style-type: none"> • 'I would be willing to prescribe or dispense unapproved medicinal cannabis products that are controlled drugs that have not undergone clinical trials.' • 'I would be willing to prescribe or dispense unapproved CBD-products that have not undergone clinical trials.' • 'I would be comfortable prescribing or dispensing unapproved medicinal cannabis products that are controlled drugs that have not undergone clinical trials.' <p>Question for prescribers:</p> <ul style="list-style-type: none"> • Do you have access to the information you need to prescribe medicinal cannabis products with confidence? • If so, is it easy to understand?

Document part	Proposals and questions
	<p>Questions for patients / consumers:</p> <ul style="list-style-type: none"> • What is your position on the following statement: "I would be comfortable taking medicinal cannabis products that have not been tested for safety and effectiveness" Please comment on whether this is true for certain types of products and not others. • Should specialist approval be required when being prescribed medicinal cannabis products? • Have you (or someone you know) been able to gain access to a specialist when required?
F	<p><u>PROPOSAL:</u></p> <p>Post market controls</p> <p>As the medicinal cannabis products are medicines, some provisions of the Medicines Act will apply.</p> <p>Questions for all:</p> <ul style="list-style-type: none"> • Please indicate your position on the following proposal: 'The current post market monitoring and compliance requirements for medicines should be applied to all medicinal cannabis products.' • Do you have any additional comments on the proposed approach to post market monitoring and compliance?
F	<p><u>PROPOSAL:</u></p> <p>Enforcement powers</p> <p>We propose that the Medicinal Cannabis Agency will have the ability to:</p> <ul style="list-style-type: none"> • vary, suspend or revoke licences • impose penalties for non-compliance with the quality standards, product information requirements or licence conditions • order the seizure and destruction of products manufactured or distributed without the relevant licence. <p>Question for all:</p> <ul style="list-style-type: none"> • Do you have any comments on the proposed enforcement powers?

Document part	Proposals and questions
F	<p><u>PROPOSAL:</u></p> <p>Collection of information</p> <p>The Medicinal Cannabis Agency will survey health practitioners about their confidence and willingness to prescribe products, the conditions that the products are being used to treat, and their effectiveness in use.</p> <p>Question for all:</p> <ul style="list-style-type: none"> In your opinion, what is the key information the agency needs to collect to monitor progress against the objectives of the Scheme?
G	<p><u>PROPOSAL:</u></p> <p>Fees</p> <p>It is proposed that the fees set under the Medicinal Cannabis Scheme enable full cost recovery of the cost of issuing licences to:</p> <ul style="list-style-type: none"> (a) Cultivate Medicinal Cannabis (b) Manufacture Medicinal Cannabis Products (c) Pack Medicinal Cannabis Products (d) Supply an Unconsented Medicinal Cannabis Product. <p>Existing licence fees under the Medicines Act and the Misuse of Drugs Act will continue to apply for existing licences.</p> <p>Question for researchers:</p> <ul style="list-style-type: none"> Will the proposed fees affect your ability to research medicinal cannabis products or cannabis? <p>Questions for industry:</p> <ul style="list-style-type: none"> Based on the proposed fees, how likely are you to enter the medicinal cannabis market? Which licence(s) do you intend to apply for within the next two years? <p>Questions for all:</p> <ul style="list-style-type: none"> What is your position on the following statement: 'The fee structure and approach are fair for both licence holders and the public.' Do you have any additional comments on the proposed approach to fees?

Appendix 1: Key terms and glossary

Approved/unapproved medicines	This is explained in 'A3: How medicinal cannabis products are currently approved and prescribed'.
CBD product	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 amounts 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)
CBN	Cannabinol. A mildly psychoactive cannabinoid found only in small amounts in cannabinoids.
Consented/unconsented medicines	This is explained in 'A3: How medicinal cannabis products are currently approved and prescribed'.
Excipients	Ingredients that are not the active ingredients of the drug.
Germplasm	Living tissue from which new plants can be grown. It can be a seed or another plant part – a leaf, a piece of stem, pollen or even just a few cells that can be turned into a whole plant.
Good manufacturing practice (GMP)	A set of principles and procedures that, when followed, helps to ensure that the therapeutic goods are of high quality. In the context of medicines, GMP refers to the <i>New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods</i> .

Harvesting	The activity of gathering or reaping a mature crop. Includes trimming of unwanted plant material.
Hemp	Cannabis plant, seed, or fruit, while a hemp product is defined as a: product of a kind that is derived, in whole or in part, from industrial hemp.
Industrial Hemp	Approved varieties of <i>Cannabis Sativa</i> that have a tetrahydrocannabinol (THC) content that is below 0.35 percent, and seeds harvested from plants of that kind.
ISO	International Organization for Standardization.
ISO 17025	A standard issued by the ISO for the general requirements for the competence of testing and calibration laboratories. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.
Medical practitioner	As used in this document, means all doctors registered by the Medical Council of New Zealand, including general practitioners and any other speciality.
Monograph	A monograph is an article that is written to deal with various aspects of a subject, such as quality requirements and test methods for cannabis.
Palliative care	World Health Organisation Definition ‘an approach to care that improves the quality of life of patients (adults and children) and their families who are facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and correct assessment and treatment of pain and other problems, whether physical, psychosocial or spiritual. Palliative care also respects the choice of patients and helps their families to deal with practical issues, including coping with loss and grief throughout the illness and in case of bereavement.’

Pharmacopoeia	An official publication containing a list of medicinal drugs with their effects and directions for their use, and the quality and performance requirements they must meet. A pharmacopoeia also describes the tests and methods that must be used.
Pharmacovigilance activities	The practice of monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported adverse reactions.
PIC/S	Pharmaceutical Inspection Co-operation Scheme – an informal arrangement by countries to cooperate in relation to inspections of pharmaceutical manufacturing facilities
Processing cannabis	Activities associated with collecting, sorting, drying, milling, de-hulling of seeds, packing of the plant material. Does not include extraction of components or constituents by physical means (eg, pressing) or chemical means (gas or solvent).
Requiring palliation	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.
Specialist	Currently for medicinal cannabis products, except for CBD-products, additional approval from a specialist working within a relevant scope of practice is required. There are 36 areas of medicine, or scopes of practice, within which you can be registered and work as a specialist in New Zealand, including as a general practitioner.
Specified substance	A substance that naturally occurs in cannabis and is THC or a related cannabinoid with psychoactive properties
Standardised product	Refers to a product which delivers a specified drug concentration and potency, and which has undergone quality control to ensure that the concentration and potency is consistent between batches of drug product.
THC	delta-9-tetrahydrocannabinol

Validation	A documented programme that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria. A validation protocol is a written plan stating how validation will be conducted and defining acceptance criteria. For example, the validation protocol for a manufacturing process identifies processing equipment, critical process parameters/operating ranges, product characteristics, sampling, test data to be collected, number of validation runs, and acceptable test results.
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Appendix 2: New Zealand Product Quality Standards Monograph

1. A product is required to meet the specifications outlined in the New Zealand Product Quality Standards Monograph (the Monograph) for:
 - (a) Active ingredients
 - (b) Terpenes
 - (c) Related substances
 - (d) Foreign material
 - (e) Microbiological contamination
 - (f) Mycotoxins
 - (g) Pesticides
 - (h) Heavy metals
 - (i) Residual solvents
 - (j) Loss on drying
 - (k) Total ash
2. The Monograph defines the applicable tests, methods, specifications and limits. These requirements are in addition to specifications outlining labelling and specific dose form requirements as set out in the following documents:
3. Additional accompanying specifications:
 - (a) Labelled according to the appropriate regulations of the Medicines Act 1984, Misuse of Drugs Act 1975 and GRTPNZ.⁴⁴
 - (b) Dose form requirements, as applicable, specified in:
 - (i) European Pharmacopoeia
 - (ii) United States Pharmacopoeia
 - (iii) British Pharmacopoeia
 - (c) Stability and shelf life according to the appropriate ICH guideline Q1A to Q1E

⁴⁴ GRTPNZ is the Ministry of Health Guideline on the Regulation of Therapeutic Products in New Zealand.

Test	Methods	Specifications
Appearance (<i>plant material</i>) ⁴⁵	<ul style="list-style-type: none"> Physical inspection⁴⁶ Macroscopic examination 	<p>Complies with physical and macroscopic examination.</p> <ul style="list-style-type: none"> Cannabis flos (depending upon variety): dark green to light green and tan coloured flowering heads of Cannabis sativa. Granulated cannabis flos: material is approximately 5 mm in diameter, or as specified.
Identification (<i>plant material</i>)	<p>The test methods include:</p> <ul style="list-style-type: none"> microscopic examination chromatographic procedures and, DNA profiling (if applicable)⁴⁷ 	Complies with the methods, including spectrographic and chromatographic techniques.
		Microscopic examination
Active ingredients (anhydrous base) ⁴⁸	<p>The test methods include:</p> <ul style="list-style-type: none"> Gas chromatography (Ph Eur. 2.2.28) or liquid chromatography (Ph Eur. 2.2.29) 	<ul style="list-style-type: none"> Herbal form (starting material): average content of each active ingredient, together with any corresponding acid, in a representative sample of the product must be not less than 80.0 % and not more than 120.0 % of the stated content of that active ingredient. Herbal form (API & finished product): average content of each active ingredient, together with any corresponding acid, in a representative sample of the product must be not less than 80.0 % and not more than 120.0 % of the stated content of that active ingredient. Other dose form (finished product): average content of each active ingredient, together with any corresponding acid, in a representative sample of the product must be not less than 90.0 % and not

⁴⁵ Plant material: as cannabis flower (flos).

⁴⁶ The cannabis inflorescence: The identification of the cannabis influence is well defined within the American Herbal Pharmacopoeia: Cannabis Inflorescence and Leaf (2013). The full and proper monograph should be consulted, this excerpt is an example only and not be relied upon as a definitive text. The European Pharmacopoeia is expected to publish a cannabis monograph in 2019, at the time of publication this should be considered the definitive text.

⁴⁷ Not a required test. A DNA profiling identification method could be required for identification of a specific clone, which is then continually propagated.

⁴⁸ Acidic cannabinoids: CBDA, CBGA, CBNA, THCA, CBCA. Neutral cannabinoids: CBG, CBD, CBN, d9THC, d8THC, CBC. (eg, CBDA is the corresponding acid to CBD). Terpenes: included if intended as an active ingredient.

Test	Methods	Specifications	
		more than 110.0 % of the stated content of that active ingredient. ⁴⁹	
Related substances (impurities)	<ul style="list-style-type: none"> Gas chromatography (Ph Eur. 2.2.28) or liquid chromatography (Ph Eur. 2.2.29) 	Impurities in New Drug Products (ICH Q3B)	
Foreign matter	<ul style="list-style-type: none"> Ph. Eur. 2.8.2: Foreign matter (plant material only) Ph. Eur. 2.8.20: Herbal drugs: sampling and sample preparation. 	<p>Contains NMT 2% foreign organs⁵⁰ or foreign elements⁵¹ (<i>plant material</i>).</p> <p>Contains NMT 0.1% foreign organs or foreign elements (<i>API and finished product</i>).</p>	
Microbiological contamination	<p>The applicable tests from:</p> <ul style="list-style-type: none"> Ph. Eur. 2.6.12: Microbial examination of non-sterile products: Microbial enumeration tests Ph. Eur. 2.6.13: Microbial examination of non-sterile products: Tests for specified micro-organisms Ph. Eur. 2.6.31: Microbial examination of herbal medicinal products for oral use and extracts used in their preparation 	<ul style="list-style-type: none"> Ph. Eur. 5.1.4: Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use. <p>The TAMC⁵² and the TYMC⁵³ are no more than the limits specified in Ph. Eur. 5.1.4, as applicable to the specific dose form, eg, inhalation, tablet etc.</p> <ul style="list-style-type: none"> No more than the limits specified in Ph. Eur. 5.1.8: Microbiological quality of herbal products for oral use and extracts used in their preparation (where Ph. Eur. 2.6.31 applies). 	
Mycotoxins	<p>Ph. Eur. 2.8.18: Aflatoxins</p> <p>Ph. Eur. 2.8.22: Ochratoxin A</p>	<p>Aflatoxin B1</p> <p>Aflatoxins B1, B2, G1, G2.</p> <p>Ochratoxin A</p>	<p>NMT 2 µg/kg</p> <p>NMT 4 µg/kg for the sum</p> <p>NMT 20 µg/kg</p>
Pesticides	<p>Ph. Eur. 2.8.13: Pesticides</p> <p>Sampling done according to Ph. Eur. 2.8.20: Herbal drugs: sampling and sample preparation.</p>	No more than the limits specified in Ph. Eur. 2.8.13: Pesticide residues.	
Heavy Metals	Ph. Eur. 2.4.27: Heavy metals	Impurities in New Drug Products (ICH Q3B)	

⁴⁹ Generally, with other medicines, on release the active content is 90-110%.

⁵⁰ Foreign organs: matter coming from the source plant but not defined as the herbal drug (eg, cannabis plant stems).

⁵¹ Foreign elements: matter not coming from the source plants and of either vegetable or mineral origin (eg, insects).

⁵² TAMC: Total Aerobic microbial count

⁵³ TYMC: Total combined yeasts/moulds count

Test	Methods	Specifications
Residual solvents	Ph. Eur. 5.4: Residual solvents.	Impurities: Guideline for Residual Solvents (ICH Q3C)
Loss on drying (<i>plant material</i>)	Ph. Eur. 2.2.32: Loss on drying	NMT 10 %
Total ash (<i>plant material</i>)	Ph. Eur. 2.4.16: Total ash	NMT 20%

Appendix 3: Medicinal Cannabis Advisory Group

In December 2018, Cabinet agreed that the Minister of Health appoint a Medicinal Cannabis Oversight Panel (the Oversight Panel) to oversee the establishment and implementation of the Scheme. The Oversight Panel has been established as the Medicinal Cannabis Advisory Group (the Advisory Group). The Minister of Health has delegated authority for the establishment and operation of the Advisory Group to the Director-General of Health. The Members of the Advisory Group are:

Name	Expertise
Dr Russell Wills Chairperson	Medical expertise – Medical Director, Quality Improvement and Patient Safety, Hawkes Bay District Health Board (HBDHB) General and Community Paediatrician, HBDHB
Suzanna Barber	Pharmacist – New Zealand registered Pharmacist, Systems Manager of the Pharmacy Service at Middlemore Hospital
Dr David Burrell	Primary care physician – General Practitioner with Special Interest in Pain Management.
Manu Caddie	Medicinal Cannabis Cultivation and Manufacturing Industry – Managing Director of Hikurangi Cannabis Company and President of New Zealand Medical Cannabis Council
Tara Creaven-Capasso	Regulatory expertise – specialises in medicinal cannabis compliance
Dr Brian Ensor	Palliative care specialist – Medical Director for Hospice Waikato in Hamilton
Professor Michelle Glass	Medicinal Cannabis Researcher – Head of the Department of Pharmacology and Toxicology at the University of Otago and Chair of the Medicinal Cannabis Research Collaborative
Judy Leader	Nurse Practitioner at MidCentral Health, involved in establishing and leading the acute pain service at MidCentral Health.
Kali Mercier	Policy – Policy and Advocacy Manager at New Zealand Drug Foundation
Rebecca Reider	Consumer representative
Dr Cynthia Sharpe	Paediatric Neurologist at Starship Hospital
Simon Royal	Chief Executive of the National Hauora Coalition

Appendix 4: New Zealand's international obligations

1. New Zealand has signed international agreements that aim to restrict production, manufacture, export, import, distribution, trade, and possession of narcotic drugs (including cannabis) exclusively to medical and scientific purposes:
 - The *Single Convention on Narcotic Drugs 1961*, which specifies the obligations of signatory countries in terms of the narcotic drugs listed in the schedules annexed to the convention
 - The *Convention on Psychotropic Substances 1971*, which aims to limit the use of psychotropic substances to medical and scientific purposes and also to ensure their availability for those purposes
 - The *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988*, which aims to promote cooperation between parties to address various aspects of illicit traffic in narcotic drugs and psychotropic substances.
2. Under the Single Convention on Narcotic Drugs 1961 (the Single Convention) as amended by its 1972 Protocol, New Zealand has an obligation to carefully control, supervise and report on various stages of cannabis cultivation, production and manufacture. The purpose of the Single Convention is to establish a framework to both prevent abuse and diversion of controlled narcotics and to facilitate the availability of such drugs for medical purposes. The enabling legislation for these obligations is the Misuse of Drugs Act 1975, which is administered by the Ministry of Health.
3. Article 5 of the Single Convention confers certain functions on the International Narcotics Control Board (INCB) which includes publication of an annual report that provides a comprehensive account of the global drug situation, analyses trends in drug abuse and drug trafficking and suggests necessary remedial action. In addition, the INCB also publishes technical reports on narcotic drugs and psychotropic substances that estimate the annual legitimate requirements of each country for these drugs, as well as data on the licit (legal) production, manufacture, trade and consumption of drugs worldwide.
4. As a signatory to the Single Convention, New Zealand is obliged to regularly provide information to the INCB to allow it to carry out these functions. Failure to meet those international obligations contains certain risks, including potential damage to New Zealand's international reputation.

5. The INCB also requires annual estimates of the areas harvested, amounts produced, amount of raw material and refined products in stock, amounts required for importing in the current and next calendar year, estimates for cultivating in the next calendar year, relevant trends in use of cannabis for medical purposes, estimates of the land area to be used for cultivation in the next year and quantities obtained by the manufacturers.
6. New Zealand, as a Member State of the Commission on Narcotic Drugs (CND), is required to report these estimates for cannabis to the INCB annually or more frequently. In order to meet these requirements, the Ministry of Health would require manufacturers to regularly report these estimates.
7. New Zealand currently has laws to regulate the import, export and manufacture of cannabinoids and cannabis, but these do not allow the lawful cultivation in New Zealand of cannabis plants for medicinal purposes.

Cultivation of cannabis

8. Presently, New Zealand is unable to grant licences for the production of locally cultivated and produced cannabis for medical use and remain compliant with the obligations in the Single Convention or the Narcotic Drugs Act.
9. Under Article 23 of the Single Convention, New Zealand is required to establish an authority to regulate the cultivation of cannabis for medicinal and scientific purposes. There are already mechanisms in place to enable access to medicinal cannabis products through the Medicines Act 1981 which allows for access to approved medicines under section 20 and 23 and unapproved medicines under clinical trials and sections 25 and 29 (for medical practitioners only).
10. Medicinal cannabis products that are controlled drugs also require Ministerial approval to prescribe under Regulation 22 of the Misuse of Drugs Regulations 1977. Ministerial approval is delegated to the Ministry of Health. General approvals can be granted to any particular case or class of cases. Currently most medicinal cannabis products (apart from CBD products) require applications for ministerial approval to prescribe.
11. The difficulty and cost of obtaining medicinal cannabis products from international suppliers, however, creates an access issue for the conduct of clinical trials and for people who may potentially benefit from using cannabis for medicinal purposes. Enabling the potential to cultivate cannabis for medicinal purposes locally will mean that there is potentially a level of supply that meets the demands for clinical trials or other access options.

Export of medicines

12. As a signatory country of the World Health Organization, New Zealand has an obligation to assure the quality of pharmaceutical products leaving its shores and moving in international commerce. As a result, medicines exported from New Zealand to other countries must be manufactured according to Good Manufacturing Practice.

Appendix 5: Canada Cannabis Regulations (Parts 5 & 6)

PART 5 Good Production Practices

General Provisions

Sale, distribution and exportation

- 79** A holder of a licence must not sell, distribute or export cannabis unless the applicable requirements set out in sections 80 to 88 have been met.

Standard operating procedures

- 80** Cannabis must be produced, packaged, labelled, distributed, stored, sampled and tested in accordance with standard operating procedures that are designed to ensure that those activities are conducted in accordance with the requirements of this Part.

Pest control product

- 81** Cannabis must not be treated with a pest control product unless the product is registered for use on cannabis under the ***Pest Control Products Act*** or is otherwise authorized for use under that Act.

Storage

- 82** Cannabis must be stored under conditions that maintain its quality.

Distribution

- 83** Cannabis must be distributed in a manner that maintains its quality.

Building or part of building

- 84 (1)** Cannabis must be produced, packaged, labelled, stored, sampled and tested in a building or part of a building that is designed, constructed and maintained in a manner that permits those activities to be conducted appropriately and under sanitary conditions, and in particular that
- (a)** permits the building or part of the building to be kept clean and orderly;
 - (b)** permits the effective cleaning of all surfaces in the building or part of the building;
 - (c)** prevents the contamination of cannabis; and
 - (d)** prevents the addition of an extraneous substance to the cannabis.

Non-application

- (2)** Despite subsection (1), cannabis may be obtained by cultivating, propagating or harvesting it outdoors.

Filtration of air

85 The building or part of the building where cannabis is produced, packaged, labelled and stored must be equipped with a system that filters air to prevent the escape of odours.

Equipment

86 (1) Cannabis must be produced, packaged, labelled, stored, sampled and tested using equipment that is designed, constructed, maintained, operated and arranged in a manner that

- (a) permits the effective cleaning of its surfaces;
- (b) permits it to function in accordance with its intended use;
- (c) prevents the contamination of the cannabis; and
- (d) prevents the addition of an extraneous substance to the cannabis.

Non-application

(2) Paragraph 1(d) does not apply to the outdoor cultivation, propagation or harvesting of cannabis.

Sanitation program

87 (1) Cannabis must be produced, packaged, labelled, stored, sampled and tested in accordance with a sanitation program that sets out

- (a) procedures for effectively cleaning the building or part of the building in which those activities are conducted;
- (b) procedures for effectively cleaning the equipment used in those activities;
- (c) procedures for handling any substance used in those activities; and
- (d) all requirements, in respect of the health and hygienic behaviour of the personnel who are involved in those activities, that are necessary to ensure that those activities are conducted in sanitary conditions.

Non-application

(2) Paragraph (1)(a) does not apply to the outdoor cultivation, propagation or harvesting of cannabis.

Quality assurance

88 (1) In the case of a holder of a licence for processing, every complaint received in respect of the quality of the cannabis must be investigated by the quality assurance person referred to in section 19 who must, if necessary, take corrective and preventative measures.

Methods and procedures

(2) In the case of a holder of a licence for processing, the cannabis must be produced, packaged, labelled, distributed, stored, sampled and tested using methods and procedures that, prior to their implementation, have been approved by a quality assurance person.

Approval prior to sale

- (3) In the case of a holder of a licence for processing, every lot or batch of cannabis must be approved by a quality assurance person before it is made available for sale.

Testing

Sale and exportation — cannabis product

- 89 A holder of a licence must not sell or export a cannabis product unless the applicable requirements set out in sections 90 to 92 have been met.

Validated methods

- 90 The testing conducted under section 91 and further to the requirements in Part 6 must be conducted using validated methods.

Composition

- 91 Testing for the following must be conducted on each lot or batch of cannabis, other than cannabis plants or cannabis plant seeds, that will become a cannabis product or that will be contained in a cannabis accessory that is a cannabis product:
- (a) the residues of solvents used in the production of cannabis oil;
 - (b) the contaminants referred to in section 94;
 - (c) the dissolution or disintegration referred to in section 95; and
 - (d) the quantity or percentage of THC, THCA, CBD and CBDA, as the case may be.

Representative sample

- 92 (1) For the purposes of the testing referred to in section 90, a representative sample of the lot or batch must be taken.

Quantity

- (2) A portion of the sample referred to in subsection (1) must be retained for at least one year after the date of the last sale of any portion of the lot or batch and must be of sufficient quantity to enable a determination of
- (a) whether the lot or batch meets the requirements of section 81, subsection 93(2) and section 94 and, if applicable, subsection 93(3) and sections 95, 97, 101 and 102; and
 - (b) the quantity or percentage of THC, THCA, CBD and CBDA, as the case may be.

PART 6 Cannabis Products

General Provisions

Substances

- 93 (1) Cannabis that is a cannabis product or that is contained in a cannabis accessory that is a cannabis product must not contain any substance other than the cannabis.

Maximum residue limit

- (2) Despite subsection (1), the cannabis may contain residues of a pest control product, its components or derivatives, if they do not exceed any maximum residue limit, in

relation to cannabis, specified for the pest control product, its components or derivatives under section 9 or 10 of the ***Pest Control Products Act***.

Cannabis oil

- (3) Despite subsection (1), cannabis oil may contain the carrier oil, residues of the solvents listed in the document entitled *Limits for Residual Solvents in Cannabis Products*, as amended from time to time and published by the Government of Canada on its website that do not exceed the limits established in that document and other substances that are necessary to maintain the oil's quality and stability.

Microbial and chemical contaminants

- 94 (1) Despite subsection 93(1), cannabis that is a cannabis product or that is contained in a cannabis accessory that is a cannabis product may contain microbial or chemical contaminants provided that they are within generally accepted tolerance limits for herbal medicines for human consumption, as established in any publication referred to in Schedule B to the ***Food and Drugs Act***.

Non-application — cannabis plant or cannabis plant seeds

- (2) The tolerance limits referred to in subsection (1) do not apply to a cannabis product that is a cannabis plant or cannabis plant seeds.

Dissolution and disintegration

- 95 Each discrete unit of a cannabis product that is intended to be administered orally, rectally or vaginally must meet the requirements of a dissolution or disintegration test that is applicable to its formulation and that is set out in any publication referred to in Schedule B to the ***Food and Drugs Act***.