

Coversheet: The Medicinal Cannabis Scheme

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| Advising agencies | Ministry of Health |
| Decision sought | The licensing framework and minimum quality standards for the Medicinal Cannabis Scheme. |
| Proposing Ministers | Hon Dr David Clark, Minister of Health |

Summary: Problem and Proposed Approach

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| <p>Problem Definition</p> <p>What problem or opportunity does this proposal seek to address? Why is Government intervention required?</p> |
| <p>The primary objective of the Medicinal Cannabis Scheme is to increase access to quality medicinal cannabis products.</p> <p>Government intervention is required to establish a regulatory scheme for the commercial production and import of products under licence. Regulations specific to medicinal cannabis will set minimum quality standards for products and set out a licensing regime to minimise the risk of diversion.</p> |

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| <p>Proposed Approach</p> <p>How will Government intervention work to bring about the desired change? How is this the best option?</p> |
| <p>The Scheme will enable the cultivation of cannabis and manufacture of medicinal cannabis products in New Zealand, and the import of overseas products.</p> <p>Government intervention is needed in these areas:</p> <ul style="list-style-type: none"> - <i>Minimum quality standards for products and processes:</i> products available through the Scheme must be made to a standard that allows them to be prescribed with confidence. Quality standards for products and manufacturing processes must be set to ensure products are consistently produced with contaminants minimised. - <i>Licensing requirements:</i> setting medicinal cannabis specific licensing requirements will minimise the risk of diversion and provide the Agency with oversight of the production and supply process, consistent with our international obligations. - <i>Prescribing requirements:</i> these need to be reviewed to ensure they balance patient access with the level of clinical oversight needed. <p>Full cost recovery of the licensing activities is proposed via licence fees. The Ministry will seek additional funding through Budget 2020 for ongoing operating costs that are not directly related to the licensing activity, such as consumer and prescriber education and guidance, and compliance and enforcement activities.</p> |

Section B: Summary Impacts: Benefits and costs

Who are the main expected beneficiaries and what is the nature of the expected benefit?

The main expected beneficiaries are patients, health practitioners and medicinal cannabis cultivators, manufacturers and suppliers.

Currently, some people are self-medicating with illicit cannabis that has been grown and processed with no quality controls.

The proposed regulatory framework will ensure that products regulated under the Scheme are made to a quality standard, that the composition is known (ie, ratio of tetrahydrocannabinol (THC)/cannabidiol (CBD) is stated, within specified limits) and that contaminants are minimised.

Health practitioners will be able to prescribe a product for a patient which has a known THC/CBD composition, and which has been produced to a specified quality standard.

New Zealand cultivators, manufacturers and suppliers will have the opportunity to enter a medicinal cannabis industry. The Ministry of Business, Innovation and Employment have provided advice that the Scheme would enable a potential domestic market of up to \$70 million and export market size of up to \$250 million.

Where do the costs fall?

A Medicinal Cannabis Agency is being established, within the Ministry of Health, to administer the licensing system and oversee the Scheme. The primary costs of the Scheme are the establishment and on-going operation of the Agency.

The Ministry received \$1.18 million from the between-Budget contingency to undertake establishment activities in 2018/19 and 2019/20. The on-going operating costs, not directly related to licensing activities, are expected to be approximately \$0.65 million per year over the first five years of the Scheme.

The on-going operational costs of the Agency will largely be met by cost recovery through the licensing system. The proposed licensing regime for the Scheme will include an overarching fee for a medicinal cannabis licence, with separate fees for activities to be undertaken under that licence. The activities include:

- cultivation of cannabis (with a separate fee for declarations of illicit seed)
- manufacture of medicinal cannabis products (including active pharmaceutical ingredients)
- supply of medicinal cannabis products (with a separate fee for the assessment by the regulator that products meet the New Zealand quality standard requirements)
- import and export of medicinal cannabis products.

Potential cultivators, manufacturers, importers, exporters and wholesalers will have to pay a fee to obtain a licence, and fees for each activity authorised by that licence. They will also have compliance costs associated with meeting the licensing requirements, continued compliance with the regulations and licence conditions, and demonstrating that products meet the quality standards.

Some of the licences under the Scheme are existing licences under the Misuse of Drugs Act (ie, import and export licences for individual consignments) and the Medicines Act (ie, licences to manufacture medicines). Where existing licences will be used under the Scheme, the current licence fees will apply.

What are the likely risks and unintended impacts, how significant are they and how will they be minimised or mitigated?

The key risks for the regulatory proposals to establish the Scheme include:

Quality standards

- The quality standards will create compliance costs for industry and this cost will be passed onto patients in the cost of products. It is important that the quality standards balance patient safety and patient access.

Licensing requirements

- If there was significant sector growth, resulting in unexpectedly high volumes of licence applications, there will be resourcing implications for the Agency to deliver on the issuing of licences within a reasonable timeframe. The Ministry has sought information through the consultation process on the number of stakeholders who intend to apply for a licence under the Scheme and will plan resources accordingly.
- If the licensing requirements are too stringent and/or too rigid, it could stifle the development of the medicinal cannabis industry and the Scheme may not deliver improved access to quality products. The Ministry is looking to have risk proportionate requirements for security and ensure requirements enable, rather than stifle industry.

Prescribing requirements

- Health practitioners may not be willing to prescribe medicinal cannabis. We will provide information on products that meet the quality standards, however the decision to prescribe should rightly remain with the clinician.

Licence fees

- Licensing fees could be a barrier to people entering the industry. This is most likely at the cultivation stage where less capital investment is needed (compared to the investment to establish a manufacturing facility) and the licence fee may be a high proportion of the set-up cost.
- The fee revenue could also be insufficient to cover the resource needed for the Agency to assess applications and issue licences and to monitor compliance with licence conditions. This could occur if the volume of licence applications is significantly lower than estimated.

Impact of recreational cannabis

- The Scheme may be impacted if the referendum vote results in the legalisation and regulation of recreational cannabis. Medicinal cannabis users may prefer to access the recreational market for products (some having been prescribed cannabis and others self-medicating). This may impact on demand for medicinal cannabis products, and on the ability to sustain a medicinal cannabis industry.
- Some medicinal producers may also wish to enter the recreational market. Demand for medicinal cannabis products, and subsequently numbers of licence applications, may be impacted.

Identify any significant incompatibility with the Government's 'Expectations for the design of regulatory systems'.

There is no incompatibility with 'Expectations for the design of regulatory systems'.

Section C: Evidence certainty and quality assurance

Agency rating of evidence certainty?

How confident are you of the evidence base?

Quality standards

There are different approaches to quality standards internationally to ensure quality at all stages of production and quality of the final medicinal cannabis product.

The value of setting quality standards for different stages of production is not universally recognised. While most jurisdictions have quality standards for manufacture and final product, not all have quality standards for cultivation or the manufacture of active pharmaceutical ingredients.

Licensing requirements

As a signatory to the United Nations Drug Conventions, New Zealand is required to have a licensing regime for the production and supply of cannabis. This is also consistent with the requirements for the supply of all controlled drugs used as medicines in New Zealand.

Prescribing requirements

The Ministry has had anecdotal feedback that the current prescribing requirements are a barrier to prescribing.

To be completed by quality assurers:

Quality Assurance Reviewing Agency:

A joint Treasury and Ministry of Health review panel has reviewed the Regulatory Impact Assessment for the above legislative/regulatory proposal in accordance with the quality assurance criteria set out in the CabGuide.

Quality Assurance Assessment:

A review panel with representatives from the Treasury Regulatory Quality Team and the Ministry of Health has reviewed the Regulatory Impact Assessment (RIA) "The Medicinal Cannabis Scheme" produced by the Ministry of Health and dated September 2019. The review team considers that it meets the Quality Assurance criteria.

Reviewer Comments and Recommendations:

The RIA shows that the Ministry has carefully considered alternative options. Implementation risks have been identified and mitigated. Stakeholders have been extensively involved in the process, and their views taken into account.

Impact Statement: The Medicinal Cannabis Scheme

Section 1: General information

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| Purpose |
| The Ministry of Health is solely responsible for the analysis and advice set out in this Regulatory Impact Statement, except as otherwise explicitly indicated. This analysis and advice has been produced for the purpose of informing final Cabinet decisions to draft the Medicinal Cannabis Regulations. |
| Key Limitations or Constraints on Analysis |
| <p>The Government has committed to introducing a Medicinal Cannabis Scheme that will improve patient access to quality products.</p> <p>The Scheme will be overseen by an Agency and all activities will be subject to a licensing regime. This meets New Zealand’s international obligations under the United Nations Single Convention on Narcotic Drugs (the Single Convention). The Single Convention requires that a government agency oversees the cultivation of cannabis for medicinal purposes.</p> <p>Assumptions</p> <p><i>Quality standards</i></p> <p>That more health practitioners will prescribe cannabis products for patients who would potentially benefit under the Scheme given the existence of readily available, quality cannabis products.</p> <p>That requiring exported products to meet minimum quality standards will enable New Zealand producers to access lucrative international markets.</p> <p><i>Licensing requirements</i></p> <p>That domestic cultivators and manufacturers, and overseas manufacturers will be interested in entering the New Zealand market and this will increase the number of quality products available. We have sought information from the sector on expectations about applying for cultivation and manufacture licences, the type (ie, dried, oils, capsules) and number of product applicants expect to produce. Over 110 applicants indicated that they intend to submit an application, but there is uncertainty over the timeframe in which such applications will be submitted.</p> <p>It is not known whether this is an under or over estimation of the initial size of the industry. Some industry stakeholders may have withheld information due to commercial interests.</p> <p><i>Prescribing requirements</i></p> <p>That the requirements for Ministry pre-approval to prescribe, and for specialist-only prescribing or for specialist endorsement to prescribe, are not necessary once the Scheme is in place and products are required to meet quality standards.</p> |

Constraints on the Cost Recovery Analysis

The licence fees have been developed based on consultation feedback on the expected number of licence applications. However, it is difficult to estimate the volume of industry activity in what is an emerging industry for New Zealand.

It is possible that there may be significantly higher numbers of applications than estimated; this was the Australian experience when estimating licence numbers for their medicinal cannabis scheme. In outyears there may be fewer industry licence holders than estimated depending on domestic and export market opportunities and the ability of licence holders to meet the quality standards set by the Scheme and by overseas markets. If the number of licence applications received is significantly different from the Ministry's estimations, a licensing fee review would be required.

Responsible Manager (signature and date):

Chris James

Medsafe

Health System Improvement and Innovation

Ministry of Health



Section 2: Problem definition and objectives

2.1 What is the context within which action is proposed?

Nature of the market

Domestic cultivation and manufacture for commercial production of medicinal cannabis is not currently permitted, except for small quantities for medical or scientific research purposes, meaning all medicinal cannabis products prescribed must be imported.

There are a range of products available internationally made to varying quality levels. Sativex (the only approved product) has been stocked domestically for a number of years and can usually be accessed by a patient within 48 hours of receiving a prescription. Prior to 2018, there were few prescriptions for medicinal cannabis products other than Sativex.

The prescribing rates of cannabis products that are stocked domestically have been steadily growing since late 2017. This was when the first supply licence was issued to a wholesaler to allow the bulk import of non-Sativex (unapproved) products.

Also in late 2017, the Misuse of Drugs Regulations were amended to remove a number of controls on CBD products. These changes removed the requirement for Ministry and specialist approval of CBD prescriptions. From this point CBD prescribing has steadily increased.

Number of prescriptions

| Year | 2017 (Sept-Dec) | 2018 (Jan-Dec) | 2019 (Jan-July) |
|------------------------------|--------------------|-------------------|--------------------|
| CBD product | 28 | 2,130 | 2,504 |
| CBD/THC or THC only products | 25 | 217 | 184 |
| Total | 53 | 2,347 | 2,688 |

As at 29 August 2019, six suppliers are licensed to hold unapproved imported cannabis products (CBD, CBD/THC and THC products). These suppliers (pharmacies and wholesalers) have supplied 14 products (11 are CBD-only products), enabling these products to be readily accessed by patients on prescription. Currently all other cannabis products must be imported as needed.

This data indicates a growing level of medicinal cannabis prescribing in New Zealand for CBD products and THC products that are available domestically.

Internationally there are growing markets in the European Union, Asia and North America for medicinal cannabis products that are made to quality standards.

Industry

While commercial cultivation of medicinal cannabis has not been permitted in New Zealand to date, a growing number of clinical research groups and industry stakeholders are cultivating cannabis plants under licence for research purposes. Currently over 10 licences

to cultivate cannabis for the purpose of medical or scientific research have been issued. It is not permitted to use cannabis cultivated under this licence for commercial purposes.

A number of stakeholders are establishing themselves as medicinal cannabis producers and intend to apply for cultivation and manufacture licences as soon as the Scheme is in operation and the Agency is able to accept applications.

New Zealand has an existing medicines manufacturing industry. Fourteen companies have licenced Good Manufacturing Practice (GMP) manufacture sites for medicines.

There is also an established industrial hemp sector in New Zealand. Some of this sector is looking to expand into cultivation for medicinal cannabis products. The cultivation, manufacture, import/export of industrial hemp for industrial uses only (food and fibre) is permitted under an industrial hemp licence.

Social context

Social and other media indicate strong public support for increased access to affordable medicinal cannabis products. The Ministry has heard from many patients through the public consultation process of their use of cannabis and the barriers to accessing quality products on prescription due to cost and prescribers who are not willing to prescribe these products.

A referendum on the legalisation of recreational cannabis will be held at 2020 election. The outcome of this referendum may impact the Scheme, particularly the demand and supply of products.

2.2 What regulatory system, or systems, are already in place?

Some medicinal cannabis products are controlled drugs and all are prescription medicines

THC is scheduled as a controlled drug under the Misuse of Drugs Act. CBD and THC are both listed as prescription medicines in the Medicines Regulations 1984. This means medicinal cannabis products can only be obtained on prescription.

While the Misuse of Drugs legislation allows controlled drugs to be used as medicines, there are requirements around access and use to minimise the risk of diversion and abuse. The cultivation and manufacture, sale, import and export of controlled drugs must be under licence. The requirement for such activities to be licensed aligns with New Zealand's international obligations under the United Nation Drug Conventions.

Under the UN Drug Conventions, New Zealand has an obligation for a government agency to control the commercial production and supply of cannabis for medical use, and to report to the International Narcotics Control Board (INCB, responsible for the implementation of the conventions) on volumes of production and manufacture.

Under the Medicines legislation products can be approved for distribution as medicines in New Zealand. The process to gain approval includes Medsafe review of the clinical trial data and review of the quality standards used to produce the product. The Medsafe approval provides assurance to medical practitioners about a product's efficacy, side

effects, the recommended dosage, and other details that enable a sound and defensible prescribing decision to be made.

Products that are not approved can still be prescribed by medical practitioners (under section 29 of the Medicines Act), but the medical practitioner must assure themselves that the product meets reasonable quality standards and that there is a clinical basis for prescribing. The current legislation does not require unapproved products to meet any quality standard. Prescribers are responsible for assessing the suitability of a particular product for a particular patient.

Other agencies with an interest in the Medicinal Cannabis Scheme

The Ministry for Business, Innovation and Employment is interested in the economic potential of a medicinal cannabis industry.

The Ministry for Primary Industries is interested in the potential impact on other horticultural crops, produce going into New Zealand's established export markets, and biosecurity of imported product.

2.3 What is the policy problem or opportunity?

Controls on the medicinal cannabis activities are needed to:

- ensure products produced under the Scheme meet the specified quality standards
- manage the risk of diversion of cannabis into the illicit market
- enable tracking and reporting to meet international commitments (UN Drug Conventions).

Review of the prescribing requirements for medicinal cannabis products is needed to test whether the current level of oversight is justified once the Scheme is in place and products are required to meet quality standards.

2.4 Are there any constraints on the scope for decision making?

The Government has stated it wants a Medicinal Cannabis Scheme that increases the availability of quality products accessed via prescription.

Cabinet agreed on 6 December 2017 to introduce a scheme that will enable domestic commercial cultivation and manufacture alongside import of overseas product.

Cabinet agreed in December 2018 that the Scheme would include licensing of all stages of production and supply, and that all products would have to meet minimum standards.

In July 2019, Cabinet agreed that a Medicinal Cannabis Agency would be established within the Ministry of Health. To ensure New Zealand meets our obligations under the UN Drug Conventions, the Agency will:

- licence growers, manufacturers, importers, and exporters of medicinal cannabis products (manufacturers and importers will also need to add a supply activity to their licence) and set conditions to minimise the risk of diversion
- monitor compliance with licence conditions, and the requirement for cannabis products to meet quality standards

- collect and report on data to the INCB about medicinal cannabis production and use in New Zealand.

The establishment of a Medicinal Cannabis Scheme does not affect the current illegal status of cannabis used recreationally (other than seed or plant material brought into the Scheme through a declaration). The Government has stated there will be a referendum on recreational use of cannabis in 2020. Regardless of the outcome of the referendum, the Government wants a Medicinal Cannabis Scheme that improves patient access to quality cannabis products that are accessed via prescription when health practitioners consider there is a potential for benefit.

2.5 What do stakeholders think?

The Ministry published the *Medicinal Cannabis Scheme public consultation document* on 10 July 2019. Public consultation ran for four weeks and closed on 7 August. The Ministry received 524 written submissions (approximately 400 from individuals and 100 from organisations).

To support the consultation, the Ministry ran information sessions for consumers and healthcare professionals in Auckland, Wellington and Christchurch, with additional sessions for industry and Māori industry in Auckland. The Ministry also held a webinar for healthcare professionals at the invitation of the New Zealand Medical Association. There were around 360 attendees across the information sessions with nearly 100 more taking part in the webinar.

Feedback

While there was a very clear majority of responses in favour of the Scheme very few endorsed it without some caveats or suggestions. Those who were “against” the Scheme tended to strongly dislike the proposals and medicine type regime. A relatively small number were philosophically opposed, while those classified as neutral tended to support the Scheme philosophy but had reservations about its workability for a variety of reasons.

Submitters who are for or against the Scheme

| For | Against | Neutral |
|-----|---------|---------|
| 267 | 64 | 72 |

There was strong agreement across all stakeholder groups for the removal of the Ministry pre-approval to prescribe THC products. In addition, many submitters from all groups requested the removal of specialist-only prescribing and the requirement for specialist endorsement to prescribe. This was supported by professional colleges and societies, including the Royal New Zealand College of General Practitioners and the Royal Australasian College of Physicians.

There were concerns about access and affordability of products, particularly from consumers and Māori. There were also concerns, particularly from Māori and smaller industry stakeholders, about barriers to entering the industry (ie, licence application requirements and licence fees).

Māori health practitioners were concerned about access due to cost and the ability for Māori to access medicinal cannabis products via local providers including rongoā Māori practitioners.

The Ministry has made a number of amendments to the proposals for licensing, quality standards and prescribing requirements following feedback from stakeholders.

Section 3: Options identification

3.1 What options are available to address the problem?

The areas of the Medicinal Cannabis Scheme considered in this Impact Assessment are:

- the minimum quality standard for cultivation, manufacture, Active Pharmaceutical Ingredients (API) and finished product
- the prescribing requirements
- the licence fees.

Quality standards

Internationally, a variety of quality standards are set for medicinal cannabis products. These range from requiring all products to be medicines grade, made to strict manufacturing standards, through to allowing patients to grow their own with no quality controls.

Quality standards for cultivation

A cultivation process quality 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 contamination (for example, pesticides, heavy metals, and mould).

Option 1 – No standard required. Cultivators could produce to any or no recognised standard

Option 2 – Manufacturers determine the desired quality for the starting material. No quality standard is set by the regulator for cultivation

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.

Under this option manufacturers could require compliance with a cultivation process standard such as Good Agricultural Practices (GAP) or set product specifications for starting materials. The requirements set would reflect the extent of processing and extraction required by the manufacturer for production of an API.

Option 3 – The regulator sets a cultivation process standard such as Good Agricultural Practice (GAP)

Under this option a process standard would be set to address the specific requirements of growing, collecting and primary processing of cannabis plants. The Agency 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. This would include:

- pesticide use
- fertilisers, growth regulators and irrigation (water quality)
- harvest, drying and processing
- destruction of unneeded organic material.

Option 4 – The regulator sets a product quality standard for starting materials

Under this option the Agency would set the New Zealand Product Quality Standard as the quality standard for starting material. The Standard specifies the kinds and amounts of ingredients the starting material may contain (or not contain, such as pesticides or heavy metals).

The cultivator would be responsible for ensuring that the starting material meets the quality standard, and would be required to provide documentation to prove this (such as a certificate of analysis). The Agency would be responsible for reviewing the evidence to verify that the starting material meets the product standard.

Quality standards for starting material intended for export

Starting material is generally the dried or cured flowers of the cannabis plant.

The domestic medicinal cannabis market is expected to be too small to support a sustainable industry. There are growing international markets for product produced to quality standards. A number of New Zealand industry stakeholders have stated export of product is a key part of their planned business models.

It is important to ensure exported product meets minimum quality standards so overseas markets have confidence in the quality of New Zealand medicinal cannabis products.

Option 1 – No standard required Cultivators could produce and export to any or no recognised standard

Option 2 – New Zealand Product Quality Standard customised for exported starting material

Testing and certificates of analysis would be required to provide evidence that products meet the quality standard. The purpose is to ensure New Zealand produced starting material reaches export markets in a state that can be used to produce quality APIs and finished products (for example, it is not contaminated with mould and pesticides).

Quality standards for manufacture process

Manufacturing standards are necessary to ensure products are consistently produced. There is a risk that the sample results from the finished product testing would not accurately represent the whole batch of products, if manufacturing quality standards are not required. In addition, manufacturing standards minimise the risks of unexpected contamination of products, incorrect labelling of products, and insufficient or too much active ingredient.

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 GMP for the manufacture of medicinal cannabis products.

Option 1 – *No standard required. Manufacturers could produce to any or no recognised standard*

Option 2 – *Current New Zealand approach: Good Manufacturing Practice for medicines (GMP)*

GMP covers all aspects of production: from the starting materials, premises and equipment to the training and personal hygiene of staff. 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. A full validation programme is required. Validation is necessary to demonstrate that products are consistently produced according to standards and specifications, both within and between batches. GMP also requires stability testing to establish the shelf life of the product.

Option 3 – *GMP and Good Production Practices (GPP): the Canadian approach*

Some stakeholders asked for an option of a different manufacture standard, such as the Canadian GPP. The purpose of an option that includes GPP is to enable manufacturers to enter the industry with lower set up costs and lower quality standard maintenance costs (compared to GMP), to enable more products to enter the New Zealand market at a lower price for patients. It is important to note that Canadian GPP currently is only applied to fresh and dried cannabis and cannabis oil.

Quality standards for active pharmaceutical ingredient (API)

A standard ensures that the quality of the active ingredients (which produce the effects of the medicines) is suitable and assured to be free of contaminants (for example, pesticides, heavy metals or moulds).

Option 1 – *No standard required. Manufacturers could produce to any or no recognised standard*

Option 2 – *the New Zealand Product Quality Standard*

Under this option, evidence that the API meets the product specifications listed in the New Zealand Product Quality Standard (a certificate of analysis) 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. This evidence would be required to be submitted to the Agency after the manufacture of the API, in conjunction with evidence that the API meets the quality standard and other requirements.

Testing and certificates of analysis are required to provide evidence that products meet the quality standard. This would be the standard for APIs entering the domestic and export markets.

Quality standards for finished products

A finished product quality standard ensures the product composition is verified (ie, the levels of THC and CBD and other APIs) and contaminants (eg, pesticides, heavy metals or mould) are minimised; the product is fit for purpose so behaves as expected when

administered; is stable over time; and ingredients that are not the active ingredients of the medicine (excipients) are suitable and free from contaminants.

Option 1 – *Status quo for imported unapproved medicines, no standard required*

Option 2 – *the New Zealand Product Quality Standard; dose form requirements; packaging and labelling requirements; stability and shelf life requirements; and excipient requirements*

The requirements for the majority of 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, the uniformity of dosage units that need to be met, and the relevant tests to undertake. This would be the standard for finished products entering the domestic and export markets.

Options considered for prescribing requirements

Medicinal cannabis products are currently only available on prescription and this requirement will continue under the Scheme.

Option 1 – status quo: pre-approval to prescribe from the Minister of Health (delegated to the Ministry of Health) and specialist endorsement, is required for most medicinal cannabis prescriptions that contain THC. Doctors are able to prescribe Sativex for its approved use (as an add-on treatment in multiple sclerosis) without approval from the Ministry. CBD products can be prescribed by all doctors without pre-approval from the Ministry or specialist endorsement.

Option 2 – remove requirement for Minister of Health (delegated to the Ministry of Health) pre-approval to prescribe for all prescriptions for THC-containing products that meet the quality standards of the Scheme but retain requirement for specialist endorsement. CBD products can be prescribed by all doctors without pre-approval from the Ministry or specialist endorsement.

Option 3 – remove requirement for pre-approval to prescribe from the Minister of Health (delegated to the Ministry of Health) and requirement for specialist endorsement for all prescriptions for THC-containing products that meet the quality standards of the Scheme. CBD and THC products can be prescribed by all doctors.

3.2 What criteria, in addition to monetary costs and benefits, have been used to assess the likely impacts of the options under consideration?

Criteria for assessing quality standard options

- impact on equitable availability (ie, does it increase or decrease the equity gap for different populations)
- impact on affordability of products
- protects patient safety
- meets health practitioners' expectations around quality
- requirements are proportionate to the level of risk
- requirements enable the development of a sustainable domestic medicinal cannabis industry that includes small and large stakeholders.

Setting quality standards will help ensure products meet health practitioners' quality expectations, and achieve patient safety. The requirement to meet the quality standard, and to provide verification to the Agency that standards are met, creates compliance costs for industry. These increased compliance costs are likely to be passed onto consumers via increased product costs. This impacts on the affordability of products.

Criteria for assessing options for prescribing requirements

- impact on equitable availability (ie, does it increase or decrease the equity gap for different populations)
- impact on affordability
- protects patient safety
- meets health practitioners' expectations around clinical management and oversight
- requirements are proportionate to the level of risk and consistent with requirements for other controlled drugs used as medicines
- requirements are transparent and easy to follow.

The prescribing requirements should balance patient access with the need for clinical oversight and management.

3.3 What other options have been ruled out of scope, or not considered, and why?

The Government has been clear that the Scheme will increase access to quality products, via prescription.

The Ministry has ruled these options out of scope:

- *No quality standard for manufacture and the final product:* quality standards are required to ensure that products are produced consistently to a quality standard. This is to meet the Scheme objective of increasing access to quality products.
- *Self-medication:* any option that enables people to self-medicate with product they have sourced themselves has not been considered. THC and CBD are prescription medicines. Under the Medicines and Misuse of Drugs legislation, THC and CBD can only be lawfully accessed by patients via prescription.
- *No prescriber oversight:* the medicinal cannabis scheme will require a prescription for medicinal cannabis. Medicinal cannabis products may have contraindications and interactions with other medicines, and clinical oversight is required to ensure patient safety.

Section 4: Impact Analysis

Marginal impact: How does each of the options identified at section 3.1 compare with the counterfactual, under each of the criteria set out in section 3.2?

| CULTIVATION QUALITY STANDARD | Option 1: No standard | Option 2: Manufacturers may determine the quality for the starting material (no standard is required by the Scheme) | Option 3: The regulator sets a cultivation process standard such as Good Agricultural Practice (GAP) | Option 4: The regulator sets a product quality standard for starting materials |
|----------------------------------------------------------------------------------|--------------------------|---------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Impact on equity of access | 0 | 0 | 0 | 0 |
| Impact on affordability of products | 0 | + | - | - |
| Protects patient safety | 0 | + | + | + |
| Meets health practitioners' expectations around quality | 0 | 0 | + | + |
| Requirements are proportionate to the level of risk | 0 | ++ | - | - |
| Requirements enable the development of a sustainable domestic medicinal cannabis | 0 | ++ | - | - |

| CULTIVATION QUALITY STANDARD | Option 1: No standard | Option 2: Manufacturers may determine the quality for the starting material (no standard is required by the Scheme) | Option 3: The regulator sets a cultivation process standard such as Good Agricultural Practice (GAP) | Option 4: The regulator sets a product quality standard for starting materials |
|-----------------------------------------------------|--------------------------|---------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| industry that includes small and large stakeholders | | process or product standard could supply manufacturers who do not require these standards. | process standard can enter the industry. | product standard can enter the industry. |
| Overall assessment | 0 | +++++ | - | ++ |

Key:

- ++ much better than doing nothing/the status quo
- + better than doing nothing/the status quo*
- 0 about the same as doing nothing/the status quo
- worse than doing nothing/the status quo
- much worse than doing nothing/the status quo

| STARTING MATERIAL FOR EXPORT QUALITY STANDARD | Option 1: No Standard | Option 2: New Zealand Product Quality Standard customised for exported starting material |
|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------------------------------------------------------------------------------------------|
| Impact on equity of access | 0 | 0 |
| Impact on affordability of products | 0 | 0 |
| Protects patient safety | 0 | 0 (improves product quality for overseas patients) |
| Meets health practitioners' expectations around quality | 0 | 0 (product exported) |
| Requirements are proportionate to the level of risk | 0 | ++ |
| Requirements enable the development of a sustainable domestic medicinal cannabis industry that includes small and large stakeholders | 0 | ++ |
| Overall assessment | 0 | ++++ |

Key:

- ++ much better than doing nothing/the status quo
- + better than doing nothing/the status quo*
- 0 about the same as doing nothing/the status quo
- worse than doing nothing/the status quo
- much worse than doing nothing/the status quo

| MANUFACTURE QUALITY STANDARD | Option 1: No standard required by Scheme | Option 2: Good Manufacturing Practice for Medicines | Option 3: Good Production Practices |
|--------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|-----------------------------------------------------|-------------------------------------|
| Impact on equity of access | 0 | 0 | 0 |
| Impact on affordability of products | 0 | - | - |
| Protects patient safety | 0 | ++ | + |
| Meets health practitioners' expectations around quality | 0 | ++ | + |
| Requirements are proportionate to the level of risk | 0 | ++ | ++ |
| Requirements enable the development of a sustainable domestic medicinal cannabis industry that includes small and large stakeholders | 0 | ++ | + |
| Overall assessment | 0 | ++++++ | +++++ |

Key:

- ++ much better than doing nothing/the status quo
- + better than doing nothing/the status quo
- 0 about the same as doing nothing/the status quo
- worse than doing nothing/the status quo
- much worse than doing nothing/the status quo

| ACTIVE PHARMACEUTICAL INGREDIENTS QUALITY STANDARD | Option 1: No standard required | Option 2: New Zealand Product Quality Standard |
|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------------------------------------------------------------------------------------------------|
| Impact on equity of access | 0 | 0 |
| Impact on affordability of products | 0 | - |
| Protects patient safety | 0 | ++ |
| Meets health practitioners' expectations around quality | 0 | ++ |
| Requirements are proportionate to the level of risk | 0 | ++ |
| Requirements enable the development of a sustainable domestic medicinal cannabis industry that includes small and large stakeholders | 0 | + Will support quality production and reduce risk of products failing the final product quality standard. |
| Overall assessment | 0 | +++++ |

Key:

- ++ much better than doing nothing/the status quo
- + better than doing nothing/the status quo
- 0 about the same as doing nothing/the status quo
- worse than doing nothing/the status quo
- much worse than doing nothing/the status quo

| FINAL PRODUCT QUALITY STANDARD | Option 1: Status quo (no standard required for unapproved medicines) | Option 2: the New Zealand Product Quality Standard; requirements for dose form, packaging and labelling, stability and shelf life, and excipients |
|--------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| Impact on equity of access | 0 | 0 |
| Impact on affordability of products | 0 | - |
| Protects patient safety | 0 | Will add to compliance costs. |
| Meets health practitioners' expectations around quality | 0 | ++ |
| Requirements are proportionate to the level of risk | 0 | ++ |
| Requirements enable the development of a sustainable domestic medicinal cannabis industry that includes small and large stakeholders | 0 | ++ |
| Overall assessment | 0 | +++++++ |

Key:

- ++ much better than doing nothing/the status quo
- + better than doing nothing/the status quo
- 0 about the same as doing nothing/the status quo
- worse than doing nothing/the status quo
- much worse than doing nothing/the status quo

| PRESCRIBING REQUIREMENTS | Option 1: status quo: pre-approval to prescribe from the Ministry of Health and specialist endorsement, for most THC products. All doctors can prescribe CBD | Option 2: if product meets quality standards remove requirement for pre-approval to prescribe but retain specialist endorsement for THC products. All doctors can prescribe CBD products | Option 3: if product meets quality standards remove requirement for pre-approval to prescribe and specialist endorsement. All doctors can prescribe THC and CBD products |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Impact on equity of access | 0 | - - There are waiting lists for some specialists, including pain specialists. Some patients have to travel to neighbouring DHBs to access specialist services. | + Especially where distance / waiting lists reduce access to specialists. |
| Impact on affordability of products | 0 | - | + Reduces transport costs and cost if decide to see a private specialist. |
| Protects patient safety | 0 | 0 | 0 GPs will consult with specialist within the scope of practice where clinically appropriate |
| Meets health practitioners' expectations around clinical management and oversight | 0 | - - | ++ supported by professional colleges and societies, including the RNZCGP and RACP |
| Requirements are proportionate to the level of risk | 0 | - - | ++ |
| Requirements are transparent and easy to follow | 0 | - | ++ |
| Overall assessment | 0 | - - - - - | + + + + + + + + |

RNZCGP (Royal New Zealand College of General Practitioners), RACP (Royal Australasian College of Physicians)

Key:

- ++ much better than doing nothing/the status quo
- + better than doing nothing/the status quo
- 0 about the same as doing nothing/the status quo
- worse than doing nothing/the status quo
- much worse than doing nothing/the status quo

Section 5: Preferred Options

5.1 What option, or combination of options, is likely best to address the problem, meet the policy objectives and deliver the highest net benefits?

The introduction of a Medicinal Cannabis Scheme that requires products to meet specified quality standards and enables commercial cultivation, manufacture and supply under licence is necessary to ensure access to quality products for New Zealand patients.

Cultivation quality standard

Consultation feedback

Both option 2 and option 3 were preferred options; there was little support for option 4 (more costly to implement as it would require setting up an auditing and certification regime to assess compliance against the standard). Option 2 was favoured by industry and researchers and is consistent with the approach taken for existing medicines that use a herbal extract as an active pharmaceutical ingredient. This is the approach taken in Australia (under a GMP manufacturing model).

The New Zealand Medicinal Cannabis Council (an industry sector organisation) noted that a process standard (Option 3) would give assurance for export markets that New Zealand starting material is a quality product. However, starting material, APIs and finished products going into export markets would have to meet the quality requirements of those markets regardless of whether New Zealand sets a quality standard.

Preferred option for the cultivation quality standard is Option 2: Cultivators meet the quality standard for starting material set by the manufacturer

This option provides the most flexibility for industry and reflects the level of risk. It recognises that different manufacturers and different export markets will want different quality standards. Industry can choose to voluntarily meet a process standard such as GAP or a starting material standard such as the New Zealand product quality standard, if this is considered useful.

Quality standard for starting material intended for export

Consultation feedback

The consultation paper proposed allowing export of starting material that met quality standards set under the Scheme. Industry submitters who were interested in exporting held mixed views on whether a New Zealand quality standard for starting material intended for export was needed or whether the requirement to meet the quality standards set by the export market was sufficient.

Preferred option is Option 2: New Zealand product quality standard customised for exported starting material

This option minimises the risk of exported New Zealand starting material reaching international markets in an un-usable or suboptimal state which could negatively impact on the export options for all New Zealand products.

Quality standard for manufacture process

Consultation feedback

Industry stakeholders favoured option 1 (GMP) by a margin over option 2 (GMP+GPP). Medical practitioners favoured GMP and consumers/patients indicated a strong preference for GMP+GPP.

Industry stakeholders in favour of option 1 (GMP) indicated they want to produce product to the highest quality standard and that GMP is generally required to enter export markets. These stakeholders considered GPP to be a lower standard.

Industry stakeholders in favour of option 2 (GMP+GPP) considered there was little difference between GMP and GPP in terms of product quality, as under both standards, products would have to meet the finished product standard. The perceived advantages of GPP included, faster timeframe to get products to market (as it doesn't require validation or stability testing), with less capital required. This was seen to be a benefit for small scale production. It was noted that limiting the manufacturing standard to GMP could limit the industry to larger corporate stakeholders and pharmaceutical companies capable of meeting GMP.

However, the Ministry considers that the capital required to establish a manufacturing plant to GPP or GMP means that small scale producers are unlikely to own their own plants. Small scale producers would likely look to contract with existing licenced manufacturers to manufacture their product to specification, and pay a fee to the manufacturer for that service. This is the model used by small scale medicine producers.

The Ministry sought information through the consultation process on the comparative costs of manufacturing the same product under GMP or GPP. There was no information specifically provided on this. It is not clear from the consultation feedback whether the cost to the public of GMP manufactured products would necessarily be higher than that of GPP manufactured products despite the potential higher cost to companies of implementing GMP.

One company submission stated that the primary driver of lower costs is economy of scale. As New Zealand is a small market, this could only be achieved by allowing products to be exported, as many overseas markets require medicinal cannabis products to meet GMP standards.

Consumers/patients favoured option 2 (GMP+GPP) arguing it would provide greater access to products and more options in terms of the form of products available (eg, fresh cannabis). Yet when asked to respond to the question of whether medicinal cannabis products should be manufactured to the same standard with regard to consistency and quality as other medicines, a clear majority of respondents, including consumers, thought this should be the case.

The majority of medical practitioners favoured option 1 (GMP) on the basis it is well established and appropriate standard for medicines. If the product quality is insufficient, patient dosing decisions could be undermined. It was noted that allowing a lower quality standard would be in conflict with the stated objective of the Scheme to improve access to quality products. A survey of 1091 medical professionals (conducted by an industry stakeholder) indicated that 85% of doctors expect medicinal cannabis products to meet GMP manufacturing quality standards in order to prescribe them.

Preferred option for the manufacture quality standard is Option 2: Good Manufacturing Practice (GMP) for medicines

There is a lack of data to support GPP providing lower set up costs for manufacture and ultimately lower cost products for patients. Establishing a GPP manufacture standard for New Zealand would create cost for the regulator, and require auditors to be trained against the standard for a small pool of manufacturers. In addition, there is a clear indication from medical practitioners that they prefer GMP products over GPP products. Given the uncertainty over whether medical practitioners would prescribe GPP products, it is not clear that there would be a sustainable market in New Zealand for GPP manufactured products.

In the absence of data to support GPP manufacture delivering lower set up costs and lower cost products for patients and medical practitioners' clear preference for GMP products, the Ministry's preferred option is manufacture to GMP only. Manufacture to GMP meets health practitioners' expectations for quality of manufacture and meets export market requirements which will support a sustainable New Zealand industry.

Quality standards for active pharmaceutical ingredients (API)

Consultation feedback

There was general agreement from all stakeholder groups that the New Zealand Product Quality Standard should be the quality standard for APIs. The quality standard lists the specifications, including the tests, methods and limits for what an API may contain.

The reasons for support centred on assurance of a consistent, quality product that aligns with existing pharmaceutical standards. Industry were supportive of the proposed API and finished product quality standards as long as the associated costs were not too restrictive, as it would enable an export market for API and finished products.

Preferred option for quality standards for active pharmaceutical ingredient (API):

Option 2 APIs are required to meet the New Zealand Product Quality Standard.

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. This standard was supported by most stakeholders and meets health practitioner expectations for quality.

Quality standard for finished product

Consultation feedback

There was general agreement that the quality standard for finished products should be the New Zealand Product Quality Standard along with the relevant dose form requirements, packaging and labelling requirements, stability and shelf life requirements and excipient requirements.

Preferred Option 2: the New Zealand Product Quality Standards; dose form requirements; packaging and labelling requirements; stability and shelf life requirements; and excipient requirements

This provides assurance of a consistent, quality product that aligns with existing pharmaceutical standards. It was supported by stakeholders, ensures patient safety and meets health practitioners' expectations for quality.

Prescribing requirements

Consultation feedback

There was a strong agreement across all stakeholders (Māori, health practitioners, patients and industry) for the removal of the requirement for Ministry of Health approval to prescribe medicinal cannabis products that meet the quality standards of the Scheme. In addition, many stakeholders from all groups requested the removal of specialist-only prescribing and the requirement for specialist endorsement for GPs to prescribe medicinal cannabis products that meet the quality standards under the Scheme.

Removal of Ministry pre-approval and specialist-endorsement was supported by a number of professional colleges and societies, including the Royal New Zealand College of General Practitioners, the Royal Australasian College of Physicians and the New Zealand Hospital Pharmacists Association.

Preferred option for prescribing requirements: Option 3 - remove requirement for pre-approval to prescribe from the Minister of Health (delegated to the Ministry of Health) and requirement for specialist endorsement for all prescriptions that contain THC for products that meet the quality standards of the Scheme. CBD and THC products can be prescribed by all doctors.

This option was supported by the majority of health practitioners, and the majority of all other stakeholders. It is not clear what value Ministry pre-approval would add to the prescribing of products that meet the quality standards. Feedback was that the requirement for specialist endorsement does not add to patient safety but does create barriers to access, particularly for those who already experience the worst health outcomes.

Feedback from some rongoā Māori practitioners was that to enable access for Māori, rongoā Māori practitioners should be able to prescribe cannabis products. THC and CBD are prescription medicines, and to date, all products other than Sativex are unapproved. Only authorised prescribers can prescribe prescription medicines and only medical practitioners can prescribe unapproved medicines. The Ministry considers the issue of rongoā Māori practitioners prescribing is broader than medicinal cannabis products and is outside the scope of the Scheme.

5.2 Summary table of costs and benefits of the preferred approach

| Affected parties (identify) | Comment: <i>nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks</i> | Impact <i>\$m present value, for monetised impacts; high, medium or low for non-monetised impacts</i> | Evidence certainty (High, medium or low) |
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------------|

Additional costs of proposed approach, compared to taking no action

| | | | |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| Regulated parties | Establishment costs to meet the licensing requirements for security and quality standards. On-going licensing and compliance costs. | High - medium set up costs for manufacture will be much higher than for cultivation. Cultivation set up costs will vary for indoor vs outdoor growing and size. | High |
| Regulators | The estimated costs for the establishment and running of the agency that will oversee the scheme. | The Ministry received \$1.118M to undertake establishment activities in 2018/19 and 2019/20. On-going operating costs are expected to be approximately \$0.65M per year for the first five years of the Scheme | Medium |
| Wider government | Ministry for Primary Industries - possible need for tertiary legislation to manage any risks around cultivation for primary industry | Low if tertiary legislation | Medium |
| Other parties | Health practitioners who undertake education and training to inform medicinal cannabis prescribing | Low to medium part of on-going education and training | Medium |
| Total Monetised Cost | | \$1.118M + \$3.25M | |
| Non-monetised costs | | | |

Expected benefits of proposed approach, compared to taking no action

| | | | |
|-------------------|---------------------------------------------------------------------|------|--------|
| Regulated parties | Enables domestic cultivation and regulation and export of products. | High | medium |
|-------------------|---------------------------------------------------------------------|------|--------|

| | | | |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| | | MBIE have provided advice that the Scheme would enable a potential domestic market of ~\$70M and export market size of ~\$250M (these numbers are estimated for a ten year time horizon). | |
| Regulators | | | |
| Wider government | | | |
| Other parties | Increases availability of quality product for patients. Increases medical practitioner confidence in the available product. | medium | medium |
| Total Monetised Benefit | | High | |
| Non-monetised benefits | | high | |

5.3 What other impacts is this approach likely to have?

The Medicinal Cannabis Scheme is expected to:

- provide employment opportunities in regions where cultivation and manufacture are undertaken. These opportunities are likely to range from labour to build fences, specialised glass houses and manufacturing plants, through to specialist manufacturing and regulatory roles.
- enable some illicit cannabis producers to move into a legal, licenced regime.
- Increase the range of products available to New Zealand patients and reduce product costs through competitive pricing.
- Provide research and development opportunities to innovate in terms of products, production and cultivation technologies.

5.4 Is the preferred option compatible with the Government's 'Expectations for the design of regulatory systems'?

The preferred option is compatible with the Government's 'Expectations for the design of regulatory systems'.

Section 6: Licences and licence fees

All stages of production and supply will be licensed under the Scheme. The proposed licensing framework for the Scheme aligns with the licensing requirements for other controlled drugs used as medicines and for the domestic production of medicines. It is also designed to ensure New Zealand meet our international obligations under the Single Convention on Narcotic Drugs 1961.

The costs of regulating licensed activities will be recovered via a licence fee. The fees quoted in this section are GST inclusive.

New or amended fee?

Some of the licenses and associated fees required for the medicinal cannabis scheme are already established and apply to other controlled drugs, medicines and associated activities. These include: licences to manufacture medicines under the Medicines Act, and licences to import and export consignments of controlled drugs under the Misuse of Drugs Act 1975. The fees for existing licences will not be amended as part of the establishment of the Scheme but could be reviewed in the future as part of a general controlled drugs and medicines fees licensing review.

A medicinal cannabis licence (and associated fees) with an activity of cultivate, manufacture, research or supply will be required to undertake the following activities under the Scheme:

- a. Research not related to commercial activities.
- b. Cultivation of cannabis plant material, with a separate fee for considering declarations of illicit seed acquired in New Zealand. The cultivation activity will cover breeding and cloning activities.
- c. Manufacture – to cover site security assessment and site audit. The manufacturer also needs to get a licence to manufacture under the Medicines Act (\$13,750 for manufacture and \$845 for packing). Manufacture will allow product development activities.
- d. Supply of product - check of site security, assessment of wholesale processes, product recall plan, pharmacovigilance plan. This activity can include supply of nursery stock, noting that this would also require a cultivation activity on the licence.

Product assessment - a separate fee to cover assessing products to verify that they comply with the quality standards and to authorise their supply. Products will then be added to the applicant's supply licence. This is required before a product enters the supply chain.

The medicinal cannabis licence and licensing of activities will be issued under the Misuse of Drugs (Medicinal Cannabis) Regulations.

Pre-screening of applications

To streamline the processing of licence applications, the Ministry proposes a pre-screening application step before applications are formally accepted by the Agency. This will screen out applications that are incomplete or contain insufficient information and allow the Agency to focus resources on applications that are complete.

An application for a licence submitted to the Agency would be charged a pre-screening fee, which is non-refundable. The pre-screening fee is \$345, which covers an

administrative assessment of the application for completeness and identifying whether there are significant gaps in the information provided (eg, company details, inclusion of Police vetting forms and identification required for vetting).

The application is either rejected (letter sent to applicant if there are significant gaps identified) or accepted (a letter and invoice for the application fee is sent to the applicant).

Once the applicant has paid the application fee, the application is assigned for assessment.

A single medicinal cannabis licence approach

The Australian Government released a review of its medicinal cannabis scheme in early September 2019. A key recommendation is to establish a single licence structure to allow some or all of cultivation, manufacture and research. The review concluded that a single licence would enable a simpler and more streamlined process for the processing of licence applications and approvals. It would also enable and provide greater flexibility for licence applicants and holders to tailor a licence to their business model and development plans.

Based on the Australian experience and feedback from consultation, the Ministry proposes a single medicinal cannabis licence for the cultivation, manufacture, research and supply activities controlled by the Medicinal Cannabis Regulations. Licence applicants who intend to manufacture controlled drugs (non-CBD medicinal cannabis products) would still be required to obtain a licence to manufacture medicines under the Medicines Act, in addition to a medicinal cannabis licence to manufacture. Export and import licences for controlled drugs are consignment specific and would be required in addition to a medicinal cannabis licence with supply activity.

The Ministry has not publicly consulted on the single licence approach or the new, reduced licence fees. The statutory deadline for regulations to be made by 18 December 2019 means further public consultation is not possible. The Ministry is confident that there will be support for the single licence approach from industry and other stakeholders as it results in reduced fees (compared with the fees outlined in the consultation document) and it streamlines requirements for licence applicants and provides greater flexibility.

Medicinal cannabis licence fee (Misuse of Drugs Act)

A single licence structure is established which authorises some or all of the activities covering research, cultivation, manufacture and supply of products (being starting material for export, active pharmaceutical ingredients, or medicinal cannabis products).

An application for a medicinal cannabis licence would require the provision of general information covering administrative matters, such as applicant and company details. The fee for a medicinal cannabis licence is \$2588 and covers an assessment of these matters, as well checking of compliance with the regulations and general licence conditions.

In addition to the medicinal cannabis licence, there will be specific requirements and an assessment fee for each licensed activity. It will be possible for a medicinal cannabis

licence to cover multiple sites, but a fee is payable for each site as each site will be assessed separately.

Cultivation activity

The consultation document proposed two types of cultivation licences based on the size of the cultivation area.

Feedback from Māori and iwi groups was that the licence fees were too high and would be a barrier to Māori participation in the medicinal cannabis industry. There was also concern that the licence fees and security requirements would be a barrier to medicinal cannabis research.

Consultation outcome

The fees for the cultivation activity would be in addition to the medicinal cannabis licence fee, and would apply regardless of the size of the site under cultivation, as the resource required for the Agency to assess the activity and visit the site would be the similar. However, the Agency will apply a risk proportionate approach to assessing the activity requirements – for example, the security requirements for low-THC crops (ie, approved hemp cultivars) may be lower than for high THC crops, depending on risks of the activity.

Based on feedback from consultation on the number of licences proposed, the Ministry has remodelled the activity fees which, along with the single medicinal cannabis licence approach (see below), has resulted in a significant reduction in the cultivation activity fees.

Declaration of illicit (illegal) New Zealand plant or seed'

The Scheme introduces a 'Declaration of illicit (illegal) New Zealand plant or seed'. This would allow cultivators who have access to illicit New Zealand cannabis plants or seeds to legally use it through making a declaration. The intent is to enable access to established New Zealand cultivars but not to create an on-going business model for illicit cannabis growers/breeders to supply illicit seed.

The Ministry proposes allowing up to 20 plants or 50 seeds per declaration. There is a charge per declaration of \$748. While the cost for the Agency to administer declarations is estimated at \$353, the Ministry has set the fee at \$748 to act as a disincentive for cultivators to use declarations as an on-going source of plants and seeds. The Agency will put the additional funding received from declarations towards fee waivers for research licences where the research is for public good.

Cost Recovery Principles and Objectives

Cost recovery principle - equity

Licensing activity fees will be paid by the people who benefit directly from the assessment and monitoring of the licensed activity. The people who are licensed to cultivate, manufacture, package and supply will generate the most benefit from their activities. They also create the greatest risk (eg, of product quality failure, of diversion) so should receive attention from the regulator, and therefore paying for regulation of the activity falls to them.

Fees should not be set at a level that favours large participants over small participants. The fees should not be a barrier to participants entering the industry.

Cost Recovery Principle - quality and safety

Compliance audits will be conducted for licence applications and renewals. Audits can also be carried out from time to time during the licence period. The fees should ensure that compliance activities to verify that licence application requirements are met are able to be conducted at reasonable intervals.

Cost Recovery Principle – efficiency

Efficiency, including timeliness, is important to ensure the policy intent (objectives) of improved access to products are met. The licencing fees should be set at a level that enables the regulator to fully recover the costs of the licensing activity (including compliance)

Cost Recovery Principle – transparency and simplicity

The people who pay the costs being recovered should be able to understand what they are paying for and why. The fee regime should not be overcomplicated.

Cost recovery principle – following public sector guidelines for charging and cost recovery.

The cost recovery fees should follow best practice (based on the Treasury guidelines for charging and cost recovery).

Objectives of cost recovery

The objectives of cost recovery via licensing fees are to:

- ensure reasonable ongoing costs of licensing industry participants are recovered, and
- ensure compliance costs for industry participants are not prohibitive.

Why cost recovery is appropriate

Cost recovery is appropriate because:

- People who hold licences as participants in the medicinal cannabis industry will directly benefit from the holding of a licence.
- The individuals or organisations who participate in the medicinal cannabis industry will undertake activities that present risks in terms of safety of products, and also in terms

of diversion of products to the illicit market. These risks are reasonable justification for Government to be involved in regulating the industry, and for the costs of regulation to be recovered from industry participants.

Nature of output

The proposed fee for each licence is based on the direct time and costs involved with the following outputs:

- assessment of the application and police vetting of applicants
- on-site audits related to the application
- monitoring that the licence holder is complying with the licence conditions.

In addition, there will be a pre-screening step before a licence application is formally accepted. This will include the receipt and screening of applications to determine completeness and quality of the information provided.

Who will be affected?

Those affected will be people/businesses who apply for licenses to cultivate medicinal cannabis and those who import, export, manufacture, supply and pack medicinal cannabis products.

Externalities

There is risk of diversion of products at all stages of production. Cannabis is generally regarded as a low risk drug, but it is illegal and the illicit market should not benefit from this Scheme through diversion of product.

It is anticipated that some people will shift from sourcing cannabis from the illicit market onto a quality product, produced under quality standards and prescribed by a medical practitioner. Access to products for those who want them and want to prescribe them will be improved.

This new industry will provide employment and business growth opportunities.

Is full or partial cost recovery proposed?

Full cost recovery of the licensing activity is proposed. The licensed activities of industry participants meet the test of being a private good and full cost recovery is appropriate.

Full cost recovery of licence activities via fees will ensure the Medicinal Cannabis Agency is resourced to carry out the licensing activities of the Scheme.

There will be ongoing operational costs of the Agency to oversee the Medicinal Cannabis Scheme. The Ministry of Health will seek additional funding through Budget 2020 of \$650k for ongoing operating costs to support aspects of the Agency's work programme in 2020/21 and beyond, including:

- communications and stakeholder engagement including website updates and prescriber guidance
- guidance for industry and industry workshops

- monitoring and reporting
- enforcement action to deal with non-compliance (eg, adding conditions, suspending or revoking a licence)
- overheads and capital depreciation.

It is not proposed to cover these operating costs through licensing fees because they are not directly related to licensing activities.

What type of fee is being proposed?

An initial licensing fee issued for one year followed by annual renewal (subject to a renewal fee) is proposed. These fees include both desk-top assessment of the application and audit and compliance activity relating to the licence.

A fee with a component of an hourly rate is not recommended because a set fee provides the industry clarity of costs whereas an hourly rate would not. The cost to industry would not be known until after each audit. It would be administratively expensive, in return for little substantial gain for either the regulator or industry.

Who will pay the cost recovery charges?

The Ministry sought information on the number of stakeholders who intended applying for cultivation and manufacture licences under the Scheme. Based on submissions the Ministry expects to receive over 110 licence applications (the projected fees in the consultation paper were based much lower volumes of licence applications).

It is estimated that applications will increase during the first four years of the medicinal cannabis scheme, eventually levelling out at a total of approximately 115 licensed industry participants.

Assessment of proposed licence fees against objectives

The proposed full cost recovery of licensing activities meets the objectives by ensuring reasonable costs are passed on, costs are not prohibitive and the Agency's activities are properly resourced.

The level of the proposed fee and its cost components

| Activity | Fee | Pre Screening (required) | Medicinal cannabis licence fee (required) |
|----------------------------------------------------------------------|---------------------------------------|----------------------------|-------------------------------------------|
| Declaration of illicit seed | \$748 | N/A | N/A |
| Cultivation | \$5,463 new \$3,393 renewal | \$345 new \$345 renewal | \$2,588 new \$2,588 renewal |
| Research (non-commercial) | No fee | | |
| Manufacture | \$3,105 new \$2,645 renewal | | |
| Supply – products (export starting material, API, finished products) | \$6,383 new \$5,923 renewal | | |
| Supply – nursery | \$748 new \$748 renewal | | |
| Product assessment – final product | \$15,410 (includes assessment of API) | N/A | N/A |
| Product assessment – API | \$7,705 | | |
| Product assessment – export starting material | \$6,038 | | |

Figures are GST inclusive

The table below shows the effort required by the Medicinal Cannabis Agency for assessing an application (by hours). The full-time-equivalent hours per application are outlined below.

| | Manufacturing Audit | Full Audit | Small Audit | Surveillance Audit | Desk Assessment | Product Assessment | Product Assessment ESM | Administration Fee | Small Desk Assessment |
|---------------|---------------------|------------|-------------|--------------------|-----------------|--------------------|------------------------|--------------------|-----------------------|
| Agency hours | 38 | 23.5 | 16.5 | 8.5 | 11.5 | 40.5 | 26 | 4 | 7.5 |
| Travel etc \$ | 1600 | 1000 | 600 | 600 | 0 | 0 | 0 | 0 | 0 |

The table below shows the activities that make up the medicinal cannabis licence fee and for each licence activity

| | Administration fee | Desk Assessment | Small Desk Assessment | Licence assessment Audit | Surveillance Audit |
|---------------------------------|--------------------|-----------------|-----------------------|--------------------------|--------------------|
| Application pre-screening | ✓ | | | | |
| Medicinal cannabis licence | ✓ | | | | |
| Research -renewal | ✓ | | | ✓ | |
| | ✓ | | | ✓ | |
| Cultivate -renewal | ✓ | ✓ | | ✓ | ✓ |
| | ✓ | | ✓ | | ✓ |
| Declaration | ✓ | | | | |
| Manufacture | ✓ | ✓ | | | ✓ |
| | ✓ | | ✓ | | ✓ |
| Supply - Nursery Seeds & Plants | | | ✓ | | |
| | ✓ | ✓ | | | ✓ |

| | | | | | |
|--------------------------------------------------|---|--|---|--|--|
| Supply - Manufactured Products -renewal | ✓ | | ✓ | | |
|--------------------------------------------------|---|--|---|--|--|

These activities directly related to licenses would be fully cost recovered.

Impact of the proposed fees

How many people, businesses, etc will be affected?

Estimated numbers of licensees are provided above. The estimates have been informed by the public consultation. Note that in addition to remodelling the fees based on the projected number of applications indicated by industry, we have also moved to a single licence model with fees attached to the licensed activity.

Risks

There is the risk that licence fees are prohibitive for small operations, and would limit the number of participants in the industry. Costs have been carefully calculated based on forecast numbers of licence applications, so that the agency can perform its functions from day one.

The risk that the Medicinal Cannabis Agency is not able to resource the processing of licence applications and renewals is moderate to high. It has been mitigated by the establishment of fees that will provide a reasonable level of resource to the Agency.

If the bid for additional Budget 2020 funding for the Agency's operational and enforcement activities is not successful, the Agency ability to undertake any operational activities would be severely constrained. This would impact on the timely processing of licence applications and New Zealand's ability to meet its UN Drug Convention obligations.

Cost recovery comparisons

Following the public consultation the fees have been remodelled to reflect submission feedback on the expected number of licence applications. The increase was most significant for the licensing of the cultivation activity which has resulted in the fees covering the cultivation activity dropping by over 50 percent.

The new fees are reasonably in-line with those that are already in place under the Misuse of Drugs Act, some of which will apply under the medicinal cannabis scheme.

Implementation Plan

Transitional arrangements for fees are not required, because the Scheme is new.

Implementation risks

There is a risk of large volumes of applications in the initial weeks. The Agency will be set up as a 'virtual agency' within the Ministry's existing structures, with activities being undertaken aligned with existing activities and capabilities. Additional resources will be required to accommodate the increase in activities as a result of Scheme implementation.

The Agency will be ready to receive applications from the date the Scheme becomes operational. The Agency intends to develop criteria to prioritise applications, such as whether the applicant already has the infrastructure in place to undertake the licensed activity.

Minimising compliance costs

Guidance will be provided, including examples of applications, to help ensure applicants are well prepared.

The enforcement strategy

The Agency will have the ability to enforce compliance with penalties such as suspending or cancelling a licence.

Section 6: Implementation and operation

6.1 How will the new arrangements work in practice?

Cultivation and manufacture will be licensed activities. Currently domestic cultivation and manufacture of cannabis for therapeutic use (other than clinical trials and research) is not allowed.

From commencement of the Scheme, the Agency will accept licence applications.

The requirement for unapproved medicinal cannabis products to meet the minimum quality standards of the Scheme will be implemented through the conditions of the supply licences issued by the Agency.

The quality standards for APIs and final products will be referred to in the Misuse of Drugs (Medicinal Cannabis) Regulations 2019. These Regulations will also set out the requirements for licences and fees.

Once implemented, responsibility for ongoing operation of the Scheme sits with the Agency within the Ministry of Health. Non-compliance with the quality standards, licensing conditions, advertising restrictions or prescribing requirements would be the responsibility of the Agency.

The illicit cultivation and supply of cannabis will remain the responsibility of the Police.

Transitional arrangements

Currently more than a dozen licences to cultivate cannabis for scientific or research purposes have been granted. The licence conditions include a requirement for all cultivars to be destroyed at the end of the licence period.

The Ministry is aware that some licence holders have been carrying out research on growing and breeding cultivars to grow commercially once the Scheme commences. In addition, some licence holders have notified the Ministry that the minimum amount of seed they could import/buy to begin their breeding research was one kilogram.

The outcome of the cultivation research would be lost if the current holders of licences are not able to retain plants and seeds for use under the Scheme. The Ministry proposes allowing these licence holders to retain 50 plants and unlimited seeds for commercial cultivation under a medical cannabis licence with cultivation as an activity.

Currently all medicinal cannabis prescriptions for New Zealand patients are for imported

products. To ensure the continued supply of imported stock under the Scheme, transition arrangements are needed.

When the Scheme commences, importers who have a current deal licence will be given 30 days to apply for a Medicinal Cannabis Licence with a supply activity. These importers will have the application pre-screening fee and the Medicinal Cannabis Licence fee waived. This recognises that as Deal Licence holders they have already been vetted by the Ministry of Health and their security arrangements checked. They will need to pay for a supply activity to be added to their licence at a cost of \$6,383. Current importers of medicinal cannabis products will have a transitional period of six months from the date the Scheme commences to provide evidence that their products meet the quality standards

Section 8: Monitoring, evaluation and review

8.1 How will the impact of the new arrangements be monitored?

Adverse events and product quality monitoring

Post-market controls in place for medicines will also apply to medicinal cannabis products. These controls include monitoring of the adverse events reported to the Centre for Adverse Reactions Monitoring; investigation of quality issues and complaints, and to have processes in place for product recalls.

Improved access to quality products

The Ministry will monitor prescribing rates of all unapproved medicinal cannabis products through the existing requirement in the Medicines Act that prescribing of all unapproved medicines are reported to Medsafe on a monthly basis.

The Ministry will commission qualitative data on prescriber views on a number of criteria including: access to products, product quality information, affordability and prescribing requirements once the Scheme has been in place for an appropriate period of time.

Industry outcomes

The Ministry will monitor the growth of the medicinal cannabis industry through monitoring the number of licences issued to cultivate, manufacture, supply, import and export. This will provide data on the number of industry stakeholders, the range and volume of products.

8.2 When and how will the new arrangements be reviewed?

The Ministry expects to review the licence fees within three to five years of implementation of the Scheme. This will be necessary as the fees have been set based on projected licence application volumes. If volumes are significantly lower or higher than projected the Ministry will either under or over cost recover and an earlier fees review would be needed.

There will be a mechanism for periodic review of the requirements under the Scheme or review in response to developments in the sector or internationally. For example, if export markets increased or decreased the quality requirements for products, the Agency may review the quality standard.

A lack of quality products entering the domestic market may prompt the Agency to review the information available to health practitioners, the quality standards and licensing requirements to ensure they are not creating an undue barrier.

If prescribing of products remained at current levels, the Agency may liaise with stakeholders to identify if there were concerns with the adequacy of the quality standard, the level of information available to health practitioners, etc.

The Ministry will monitor patient and health practitioner satisfaction with the Scheme to identify whether it is meeting its objective of increasing access to quality products.

