Coversheet: Medicinal cannabis: 100 day action

Advising agencies	Ministry of Health
Decision sought	Introduction of Misuse of Drugs Amendment Bill
Proposing Ministers	Hon Dr David Clark, Minister of Health

Medicinal Cannabis 100 day action

Summary: Problem and Proposed Approach

Problem Definition **What problem or opportunity does this proposal seek to address? Why is Government intervention required?**
Despite a legal pathway, access to affordable medicinal cannabis products remains problematic. There is sometimes a reluctance by medical practitioners to prescribe medicinal cannabis because of a lack of evidence of efficacy. Accessing suitable products made to quality standards, and the cost of those products, are also barriers to access to medicinal cannabis. Some people choose to self-medicate with illicit cannabis, without medical oversight.

Proposed Approach **How will Government intervention work to bring about the desired change? How is this the best option?**
The Government has a 100-day commitment to introduce legislation to enable access to medicinal cannabis for people with a terminal illness or chronic pain. The proposed approach is based on the principles of equity, quality and safety, and compassion. Based on these principles, a Misuse of Drugs (Medicinal Cannabis) Amendment Bill is proposed to: i. introduce an exception and a statutory defence for terminally ill people to possess and use illicit cannabis, ii. introduce provisions allowing regulations to be made for a medicinal cannabis scheme that enables access to products made to a quality standard in a timely way, and iii. deschedule cannabidiol as a controlled drug. The proposed legislation will: • provide that a person who possesses or uses Class B or Class C cannabis products, including cannabis oil and plant material, does not commit an offence if the person has a certificate from a medical practitioner certifying that the person

has a terminal illness, and

- provide a defence against prosecution for use and possession of Class B or C cannabis products, including cannabis oil and plant material, where the person is unable to produce evidence of a terminal illness if questioned by Police.

A further Impact Assessment for the detail of a medicinal cannabis scheme, expected to include the establishment of a government agency for domestic production of medicinal cannabis and enabling standards to be set, will be provided when further detail has been developed. An initial report is to be provided in March 2018. This paper deals with the inclusion of regulation making powers included in the Bill.

The impact of the proposal to deschedule CBD is expected to be minor in practice. The amendment removes requirements and does not create any new ones.

Section B: Summary Impacts: Benefits and costs

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

Monetised and non-monetised benefits

The proposed changes to the Misuse of Drugs Act 1975 will benefit the terminally ill, who use, or intend to use, illicit cannabis products. Introduction of an exception and statutory defence will provide a level of comfort and reassurance to the terminally ill that they may possess and use illicit cannabis without fear of prosecution.

The regulation making power to enable a medicinal cannabis scheme that enables access to products made to a quality standard in a timely way will benefit medical practitioners and their patients who wish to have access to cannabis products. Costs and benefits of the medicinal cannabis scheme will be addressed in the planned March paper when further detail of the proposed scheme is developed.

Where do the costs fall?

There may be resource requirements for NZ Police, as investigating whether there is a valid defence will use operational time. There may be some impact on Court resources if a terminally ill person defends a charge.

There may be a small cost to terminally ill people who wish to access illicit cannabis in obtaining a medical certificate or letter to prove they are terminally ill.

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

The implementation of the proposed provisions for the exception and defence carries little risk and any unintended impacts are estimated to be low. Some terminally ill people not currently using illicit cannabis may now decide to do so.

The risks and unintended consequences of the regulation making power include the possibility that the scope of the power is too narrow or too broad. There may be impacts, intended or otherwise on other regulatory powers. These should be further considered in the March 2018 report.

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?
It is well known that some people who are close to the end of their life are using illicit cannabis to relieve their symptoms. While there are potential health and safety risks for people consuming illicit cannabis, the circumstances of people with a terminal illness are different. The proposed interim legislative change will be reviewed two years after the new provisions come into force.

To be completed by quality assurers:

Quality Assurance Reviewing Agency:
Regulatory Quality Team, The Treasury
Quality Assurance Assessment:
Not applicable for 100-day priorities.
Reviewer Comments and Recommendations:
The Regulatory Quality Team at the Treasury has reviewed the Regulatory Impact Statement "Medicinal Cannabis: 100-day action" by the Ministry of Health in accordance with arrangements for 100-day plan priorities. The Regulatory Impact Statement sets out the current position as regards the use of cannabis for medicinal purposes and how the proposed legislation is intended to provide comfort for a specific class of users by providing an exception and statutory defence for terminally ill people. As noted in the section "Key Limitations or Constraints on Analysis", there is a lack of information about current patterns of usage and demand, including demand that is currently suppressed by legal restrictions, which limits assessment of the likely impacts of lifting those legal restrictions. The RIS does not analyse the nature and scope of the proposal for a medicinal cannabis scheme. This raises the risk that it may be necessary to reconsider these questions in the course of the detailed design of that scheme, which is to be considered later. It will also be important to monitor and take into account any evidence of changes in demand and supply patterns following the introduction of the exception and statutory defence, in the development and eventual management of the proposed medicinal cannabis scheme.

Impact Statement: Medicinal Cannabis 100-day action

Section 1: General information

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 decisions to proceed with a policy change to be taken by Cabinet.

Key Limitations or Constraints on Analysis
There is a lack of accurate information about the demand for cannabis products from terminally ill people and other patient groups. Social and other media indicate strong public support for improved access to cannabis for patients, particularly terminally ill people. In preparing its advice, the Ministry has considered medicinal cannabis regimes from other jurisdictions, current practice, and the levers available in the existing law. The 100-day commitment to the introduction of legislation imposes a tight time frame. In order to meet timing constraints and bring about change comparatively quickly, an interim compassionate step is proposed. Consultation with key stakeholders has been carried out, but wider consultation has not been possible in the timeframe available.

Responsible Manager (signature and date):

Section 2: Problem definition and objectives

2.1 What is the context within which action is proposed?

Cannabis is regulated as a Class B1 and a Class C controlled drug under the Act, and is subject to controlled drug requirements. The Act seeks to enable access to controlled drugs used therapeutically, while having controls to prevent misuse and diversion.

New Zealand has a therapeutic model of accessing cannabis. There is a pathway to access both pharmaceutical and non-pharmaceutical grade cannabis products, based on efficacy data and clinical judgment.

Patients can access medicinal cannabis through prescription from a doctor who, in most instances, must apply to the Ministry of Health for approval to prescribe and then need to locate and import a product.

Cannabidiol (CBD) products can be accessed directly from a doctor via prescription. Secondly, clinicians can prescribe Sativex to treat spasticity associated with Multiple Sclerosis without pre-approval from the Ministry. Prescribing Sativex for any other condition requires Ministry approval on a case by case basis. No other cannabis products are consented.

There are a range of products available internationally made to varying quality levels. They range from Sativex and Bedrocan, which are pharmaceutical grade products that meet good manufacturing practice, through to leaf cannabis available from a dispensary (for example, in California) or grown by an individual.

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

The Misuse of Drugs Act, and associated Regulations govern the supply, possession and use of cannabis and medicines and other controlled drugs.

NZ Police, Ministry of Justice, and the New Zealand Customs Service have a substantive interest in the regulation of controlled drugs. Police and Justice are interested in ensuring that enforcement of the legislation is workable, particularly for the statutory defence. Customs have an interest in border control of cannabis products imported into New Zealand, but there will be no impact on import and export requirements from the proposals.

The overall fitness-for-purpose of the system will be assessed when the Act and Misuse of Drugs Regulations are next reviewed.

2.3 What is the policy problem or opportunity?

The Government 100-day Plan commits to introducing legislation to make medicinal cannabis available for people with terminal illnesses or in chronic pain.

New Zealand patients face difficulties accessing cannabis-based products. Under the current legal pathway, people can be prescribed a cannabis product if their medical practitioner supports its use for that individual.

Prescribers are likely to be cautious towards new products where evidence of efficacy is limited and side-effects uncertain. It is also likely that the process to obtain pre-approval to prescribe, source a product (made to a quality standard with the desired composition), and arrange import, are further barriers for medical practitioners.

There are a limited range of products available that are made to quality standards and strict

controls around the import and export of cannabis products internationally. The cost can be prohibitive with Sativex costing $1100 to $1400 per month, depending on dose. No cannabis product is subsidised by PHARMAC.

These barriers are best addressed in the long term by the establishment of a medicinal cannabis scheme.

Some people choose to self-medicate with illicit cannabis without clinical oversight.

2.5 What do stakeholders think?

The following departments and agencies have been consulted on the policy proposals for the Misuse of Drugs (Medicinal Cannabis) Amendment Bill prior to the 6 December Cabinet Business Committee meeting: Ministry for Vulnerable Children Oranga Tamariki, New Zealand Customs, Accident Compensation Corporation, Te Puni Kōkiri, Ministry for Primary Industries, Department of Prime Minister and Cabinet, Treasury, PHARMAC, Ministry for Pacific Peoples, and the Ministry of Business, Innovation and Employment.

NZ First and the Green Party were consulted on the policy proposals for the Misuse of Drugs (Medicinal Cannabis) Amendment Bill prior to the 6 December Cabinet Business Committee meeting.

Treasury, the Ministry of Justice and NZ Police have been consulted on the Misuse of Drugs (Medicinal Cannabis) Amendment Bill.

Police have raised the issue that it is essential the provisions are workable, and officials will continue to work together to ensure that they are.

Section 3: Options identification

3.1 What options are available to address the problem?

In preparing its advice, the Ministry has considered medicinal cannabis regimes from other jurisdictions, current practice, and the levers available in the existing law. In order to meet timing constraints and bring about change comparatively quickly, an interim compassionate step is proposed. This will allow terminally ill people who have a very particular risk profile to use illicit cannabis if they want to, without fear of prosecution.

A Misuse of Drugs (Medicinal Cannabis) Amendment Bill is proposed to:

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

ii) introduce provisions allowing regulations to be made for a medicinal cannabis scheme that enables access to products made to a quality standard in a timely way, and

iii) deschedule cannabidiol as a controlled drug.

The proposed legislation will:

- provide that a person who possesses or uses Class B or Class C cannabis products, including cannabis oil and plant material, does not commit an offence if the person has a certificate from a medical practitioner certifying that the person

has a terminal illness, and

- provide a defence against prosecution for use and possession of Class B or C cannabis products, including cannabis oil and plant material, where the person is unable to produce evidence of a terminal illness if questioned by Police.

The impact of the proposal to deschedule CBD is expected to be minor in practice. The amendment removes requirements and does not create any new ones.

The introduction of a comprehensive medicinal cannabis scheme will be reported on in March 2018. An Impact Analysis for establishment of the agency for domestic production of medicinal cannabis and enabling standards to be set for medicinal products and other functions will be prepared, following further details being confirmed in the report.

Requiring medicinal cannabis products to meet a quality standard could be achieved either through changing legislation (creating a regulation making power), or through a non-legislative approach, such as by setting a voluntary quality standard. We consider that it is necessary to establish the Scheme through changing legislation.

Medicinal cannabis products, as is the case with any therapeutic product, may present serious risk of harm, especially if used inappropriately. For instance, the use of medicinal cannabis products may impact on the metabolism of other medicines, products can contain contaminants and may not be true-to-label. It is not reasonable to expect individuals to have the knowledge to assess the quality of a product or the likelihood that the composition is as stated. Given these concerns, we think a voluntary mechanism would be insufficient to protect the public, and inconsistent with the requirements for other therapeutic products, such as medicines.

In addition, there is a rapid development of new medicinal cannabis products of varying quality, so it is important that Government has oversight to ensure products that may be widely used are safe.

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

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

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

The intent is not to increase the number of terminally ill people who access illicit cannabis, and self-medicate without clinical oversight. The intent is to provide comfort and reassurance to terminally ill people who choose to access illicit cannabis.

This proposal does not provide a defence for terminally ill people to import or cultivate cannabis nor does it provide a defence for those who supply cannabis to terminally ill people. An exception and/or statutory defence for family/whanau and friends who access illicit cannabis on behalf of a terminally ill person would change legislation for supply, which carries significantly higher penalties than for possession and use. An exception or statutory defence is not proposed for this group. The proposed medicinal cannabis scheme is the mechanism to enable access to readily available and affordable cannabis products made to a quality standard.

It is not proposed to extend the exception and statutory defence to people in chronic pain.

Chronic pain is difficult to define, subjective, and would potentially cover a large patient group (21 percent of adults experience chronic pain). Extending this proposal to this group would be likely to result in significant legal dispute around the definition of chronic pain.

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

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? *Add, or subtract, columns and rows as necessary.*

Criterion	No action	Option: Exemption and defence
equity	**0**	**0** about the same as doing nothing/the status quo
quality and safety	**0**	**0** about the same as doing nothing/the status quo
compassion	**0**	**++** much better than doing nothing/the status quo
Overall assessment		**+** better than doing nothing/the status quo

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: Conclusions

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?
Providing a medicinal cannabis scheme, including setting up a government agency, improves on current process and availability for all people who wish to use medicinal cannabis. This is the best longer term solution to meet the Government's aim of improving access to medicinal cannabis for people who are terminally ill or in chronic pain. Allowing terminally ill people who have a very particular risk profile to use illicit cannabis if they want to, without fear of prosecution, is an interim compassionate step.

5.2 Summary table of costs and benefits of the preferred approach

Affected parties	Comment	Impact	Evidence certainty
Additional costs of proposed approach, compared to taking no action			
Regulated parties		Low	Low
Regulators	Minimal cost to NZ Police, Court system	Low	Low
Wider government	Nil	Low	Low
Other parties		Low	
Total Monetised Cost	Minimal	Low	Low
Non-monetised costs	Low	Low	Low
Expected benefits of proposed approach, compared to taking no action			
Regulated parties	Enable level of comfort for terminally ill people who wish to use illicit cannabis	Low	Medium
Regulators			
Wider government			
Other parties		Low	Low
Total Monetised Benefit			
Non-monetised benefits		*(High, medium or low)*	

5.3 What other impacts is this approach likely to have?
Implementation of the exemption and defence is unlikely to have other impacts.

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

Section 6: Implementation and operation

6.1 How will the new arrangements work in practice?
An amendment to the Misuse of Drugs Act is proposed. The Ministry will provide communications messages along with stakeholders. No transitional arrangements are required before the legislation is enacted. NZ Police will be largely responsible for ongoing operation and enforcement of the new provisions, along with the Court system.

6.2 What are the implementation risks?
The exemption and defence are expected to provide comfort and reassurance to terminally ill people who choose to use illicit cannabis. Communications material will emphasis this.

Section 7: Monitoring, evaluation and review

7.1 How will the impact of the new arrangements be monitored?
Courts information will be monitored.

7.2 When and how will the new arrangements be reviewed?
The exemption and defence provisions in the Act will be reviewed two years after they come into force.