

## Disclosure Statement Template for a Government Bill

# Departmental Disclosure Statement

Misuse of Drugs (Medicinal Cannabis) Amendment Bill

The departmental disclosure statement for a government Bill seeks to bring together in one place a range of information to support and enhance the Parliamentary and public scrutiny of that Bill.

It identifies:

- the general policy intent of the Bill and other background policy material
- some of the key quality assurance products and processes used to develop and test the content of the Bill, and
- the presence of certain significant powers or features in the Bill that might be of particular Parliamentary or public interest and warrant an explanation.

This disclosure statement was prepared by the Ministry of Health.

The Ministry of Health certifies that, to the best of its knowledge and understanding, the information provided is complete and accurate at the date of finalisation below.

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## Part One: General Policy Statement

The Bill is the Misuse of Drugs (Medicinal Cannabis) Amendment Bill. It amends the Misuse of Drugs Act 1975. The Bill will—

- introduce an exception and a statutory defence for terminally ill people to possess and use illicit cannabis and to possess a cannabis utensil; and
- provide a regulation-making power to enable the setting of standards that products manufactured, imported, and supplied under licence must meet; and
- deschedule cannabidiol (CBD) and CBD products so that they are no longer controlled drugs.

These measures are part of the new Government's 100-day plan after the 2017 general election. The measures are intended to improve access to medicinal cannabis and are guided by the principles of fairness, quality and safety, and compassion.

While there is a legal pathway for people to obtain cannabis on prescription from a medical practitioner, access to affordable cannabis products remains problematic for New Zealanders.

Providing an exception and a statutory defence for terminally ill people to possess and use illicit cannabis and a statutory defence to possess a cannabis utensil is intended as a compassionate measure until affordable quality products are available under a proposed medicinal cannabis scheme. It is well known that some terminally ill people are choosing to self-medicate with illicit cannabis. The provisions are not intended to encourage terminally ill people to use illicit cannabis. The intent is to provide reassurance to terminally ill people who have, or who intend to, use illicit cannabis despite the legal prohibition.

The Bill also establishes a regulation-making power to set quality standards for domestically manufactured and imported cannabis products. Most cannabis products produced internationally do not meet the quality and efficacy requirements of therapeutic product regulators such as Medsafe. The ability to set and require minimum quality standards for cannabis products will improve patient safety and give medical practitioners confidence about the available products.

Cannabidiol (CBD) is a substance found in cannabis that has potential therapeutic value and little or no psychoactive properties. Descheduling CBD, making it a prescription medicine only, reflects the advice of the Expert Advisory Committee on Drugs. The Committee also advised a CBD product could have an allowed contamination level of other natural cannabinoids up to 2% of the total cannabinoid content. This acknowledges that there is no pure cannabidiol product made to reliable quality standards currently available.

## Part Two: Background Material and Policy Information

### Published reviews or evaluations

<b>2.1. Are there any publicly available inquiry, review or evaluation reports that have informed, or are relevant to, the policy to be given effect by this Bill?</b>	<b>YES</b>
<p>The Expert Advisory Committee on Drugs' advice to the then Associate Minister of Health on the classification of CBD, dated 14 February 2017, is available on the Ministry of Health's website.</p> <p><a href="http://www.health.govt.nz/new-zealand-health-system/key-health-sector-organisations-and-people/ministerial-health-committees/national-drug-policy-committees#eacd26oct">http://www.health.govt.nz/new-zealand-health-system/key-health-sector-organisations-and-people/ministerial-health-committees/national-drug-policy-committees#eacd26oct</a></p>	

### Relevant international treaties

<b>2.2. Does this Bill seek to give effect to New Zealand action in relation to an international treaty?</b>	<b>NO</b>
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### Regulatory impact analysis

<b>2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this Bill?</b>	<b>YES</b>
<p>Impact Statement: Medicinal Cannabis 100-day Action, Ministry of Health, 14 December 2018. The RIS will be available on the Treasury website at:</p> <p><a href="http://www.treasury.govt.nz/publications/informationreleases/ris">http://www.treasury.govt.nz/publications/informationreleases/ris</a></p> <p>and on the Ministry of Health website at:</p> <p><a href="http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements">http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements</a></p>	

<b>2.3.1. If so, did the RIA Team in the Treasury provide an independent opinion on the quality of any of these regulatory impact statements?</b>	<b>YES</b>
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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.

<b>2.3.2. Are there aspects of the policy to be given effect by this Bill that were not addressed by, or that now vary materially from, the policy options analysed in these regulatory impact statements?</b>	<b>YES</b>
<p>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 early 2018. This paper deals with the inclusion of regulation making powers included in the Bill.</p> <p>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.</p>	

**Extent of impact analysis available**

<b>2.4. Has further impact analysis become available for any aspects of the policy to be given effect by this Bill?</b>	<b>NO</b>

<b>2.5. For the policy to be given effect by this Bill, is there analysis available on:</b>	
<b>(a) the size of the potential costs and benefits?</b>	<b>NO</b>
<b>(b) the potential for any group of persons to suffer a substantial unavoidable loss of income or wealth?</b>	<b>NO</b>
<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>None of the provisions in the Bill would cause business or individuals to suffer a substantial or unavoidable loss of income or wealth.</p>	

<b>2.6. For the policy to be given effect by this Bill, are the potential costs or benefits likely to be impacted by:</b>	
<b>(a) the level of effective compliance or non-compliance with applicable obligations or standards?</b>	<b>NO</b>
<b>(b) the nature and level of regulator effort put into encouraging or securing compliance?</b>	<b>NO</b>
<p>The Bill extends an exception and a statutory defence for terminally ill to possess and use illicit cannabis, creates a mechanism to set quality standards for products by regulation and deschedules CBD. As such the issue of compliance does not arise.</p>	

## Part Three: Testing of Legislative Content

### Consistency with New Zealand's international obligations

**3.1. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with New Zealand's international obligations?**

The exception and statutory defence provisions are consistent with New Zealand's obligations under the United Nations' Drug Conventions.

### Consistency with the government's Treaty of Waitangi obligations

**3.2. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with the principles of the Treaty of Waitangi?**

No issues were identified in the development of the policies that may have specific implications for the rights and interests of Māori protected by the Treaty of Waitangi. As such, no formal steps have been taken to determine whether the policies to be given effect by this Bill are consistent with the principles of the Treaty of Waitangi.

### Consistency with the New Zealand Bill of Rights Act 1990

**3.3. Has advice been provided to the Attorney-General on whether any provisions of this Bill appear to limit any of the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990?**

YES

Advice provided to the Attorney-General by the Ministry of Justice is generally expected to be available on the Ministry of Justice's website upon introduction of a Bill. Such advice will be accessible on the Ministry's website at <http://www.justice.govt.nz/policy/constitutional-law-and-human-rights/human-rights/bill-of-rights/>

## Offences, penalties and court jurisdictions

<b>3.4. Does this Bill create, amend, or remove:</b>	
<b>(a) offences or penalties (including infringement offences or penalties and civil pecuniary penalty regimes)?</b>	<b>YES</b>
<b>(b) the jurisdiction of a court or tribunal (including rights to judicial review or rights of appeal)?</b>	<b>NO</b>
The exception and statutory defence for terminally ill people to possess and use illicit cannabis amends section 7 of the Misuse of Drugs Act.	

<b>3.4.1. Was the Ministry of Justice consulted about these provisions?</b>	<b>YES</b>
The Ministry of Justice was consulted on the policy as part of the Cabinet Business Committee paper and on the Amendment Bill.	

## Privacy issues

<b>3.5. Does this Bill create, amend or remove any provisions relating to the collection, storage, access to, correction of, use or disclosure of personal information?</b>	<b>NO</b>

<b>3.5.1. Was the Privacy Commissioner consulted about these provisions?</b>	<b>NO</b>

## External consultation

<b>3.6. Has there been any external consultation on the policy to be given effect by this Bill, or on a draft of this Bill?</b>	<b>NO</b>
While there was no specific consultation on the policy that is given effect in this Bill, improving access to medicinal cannabis was part of the new Government's manifesto commitments.	

### Other testing of proposals

<b>3.7. Have the policy details to be given effect by this Bill been otherwise tested or assessed in any way to ensure the Bill's provisions are workable and complete?</b>	<b>YES</b>
<p>Police have been consulted to ensure the proposals are workable from an enforcement perspective. The Ministry will continue to work with Police, as well as other agencies and health practitioners to develop guidelines for terminally ill people, medical practitioners, nurse practitioners and enforcement agencies.</p>	

## Part Four: Significant Legislative Features

### Compulsory acquisition of private property

<b>4.1. Does this Bill contain any provisions that could result in the compulsory acquisition of private property?</b>	<b>NO</b>

### Charges in the nature of a tax

<b>4.2. Does this Bill create or amend a power to impose a fee, levy or charge in the nature of a tax?</b>	<b>NO</b>

### Retrospective effect

<b>4.3. Does this Bill affect rights, freedoms, or impose obligations, retrospectively?</b>	<b>NO</b>

### Strict liability or reversal of the usual burden of proof for offences

<b>4.4. Does this Bill:</b>	
<b>(a) create or amend a strict or absolute liability offence?</b>	<b>NO</b>
<b>(b) reverse or modify the usual burden of proof for an offence or a civil pecuniary penalty proceeding?</b>	<b>YES</b>
<p>The exception means that a person, who has certification from a medical practitioner or nurse practitioner that they are terminally ill, will not commit an offence if they possess or use illicit cannabis. The statutory defence is a defence against prosecution where a person is unable to produce immediate evidence of a terminal illness at the time of questioning by Police, but is able to produce evidence in court.</p> <p>The onus is on the terminally ill person to provide evidence that the exception or statutory defence applies.</p>	

### Civil or criminal immunity

<b>4.5. Does this Bill create or amend a civil or criminal immunity for any person?</b>	<b>YES</b>
Section 5 of the Bill creates a criminal immunity for terminally ill people who possess and use illicit cannabis.	

### Significant decision-making powers

<b>4.6. Does this Bill create or amend a decision-making power to make a determination about a person's rights, obligations, or interests protected or recognised by law, and that could have a significant impact on those rights, obligations, or interests?</b>	<b>NO</b>

### Powers to make delegated legislation

<b>4.7. Does this Bill create or amend a power to make delegated legislation that could amend an Act, define the meaning of a term in an Act, or grant an exemption from an Act or delegated legislation?</b>	<b>No</b>

<b>4.8. Does this Bill create or amend any other powers to make delegated legislation?</b>	<b>YES</b>
<p>Section 6 of the Bill creates a regulation-making power to enable the setting of standards that products manufactured, imported, and supplied under licence must meet.</p> <p>This will allow the setting of minimum quality standards for both domestically produced and imported cannabis products.</p> <p>Very few cannabis products have been assessed by a therapeutic regulator such as Medsafe or the Food &amp; Drugs Administration.</p> <p>The ability to set and require minimum quality standards for cannabis products will improve patient safety and give medical practitioners confidence about the products available under a Medicinal Cannabis Scheme.</p>	

### Any other unusual provisions or features

<b>4.9. Does this Bill contain any provisions (other than those noted above) that are unusual or call for special comment?</b>	<b>NO</b>