

# Departmental Disclosure Statement

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## Misuse of Drugs (Medicinal Cannabis) Amendment Bill

The departmental disclosure statement for a Government Supplementary Order Paper (SOP) seeks to bring together in one place a range of information to support and enhance the Parliamentary and public scrutiny of that SOP.

It identifies:

- the general policy intent of the SOP and other background policy material;
- some of the key quality assurance products and processes used to develop and test the content of the SOP;
- the presence of certain significant powers or features in the SOP 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

This Supplementary Order Paper (**SOP**) amends the Misuse of Drugs (Medicinal Cannabis) Amendment Bill.

As introduced, the Bill provided an exception and a defence to the offence of possessing and using cannabis for people with a terminal illness. This SOP proposes to broaden the exception and defence so that they apply to people who require palliation. A person requires palliation if, in the opinion of a medical practitioner or nurse practitioner, the person has an advanced progressive life-limiting condition and is nearing the end of their life.

This SOP proposes to give further guidance about the regulation-making power to prescribe minimum quality standards for products that contain controlled drugs. The proposed amendments—

- allow minimum quality standards to be prescribed for a product or for the processes by which a product is cultivated, manufactured, produced, imported, or supplied; and
- allow minimum quality standards to apply generally to a product, or only if specified criteria are met; and
- ensure that minimum quality standards that relate to products containing cannabis cannot require that the variety of plant contained in the product was brought into New Zealand with authorisation, if the variety is established in New Zealand at the time the product is manufactured or produced; and
- require the Minister of Health to recommend the making of regulations setting minimum standards for products containing cannabis no later than 1 year after the date on which the Bill comes into force.

This SOP also proposes—

- to exempt substances that naturally occur in cannabis from being controlled under the Misuse of Drugs Act 1975 if the substances are not capable of inducing more than a minor psychoactive effect; and
- to amend the definition of CBD product to reflect that such products may potentially contain small amounts of THC-related psychoactive substances.

## 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 SOP?</b>	<b>NO</b>

### Relevant international treaties

<b>2.2. Does this SOP seek to give effect to New Zealand action in relation to an international treaty?</b>	<b>NO</b>

### Regulatory impact analysis

<b>2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this SOP?</b>	<b>NO</b>
The Regulatory Quality Team has determined that a Regulatory Impact Assessment is not required, as the proposals are expected to have no or only minor impacts on businesses, individuals or not-for-profit entities.	

<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>n/a</b>

<b>2.3.2. Are there aspects of the policy to be given effect by this SOP that were not addressed by, or that now vary materially from, the policy options analysed in these regulatory impact statements?</b>	<b>n/a</b>

### 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 SOP?</b>	<b>NO</b>

<b>2.5. For the policy to be given effect by this SOP, 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 people requiring palliation, 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 people requiring palliation that they may possess and use illicit cannabis without fear of prosecution.</p> <p>The change from 'terminal illness' to 'palliation' is expected to increase the number of people covered by the exception and statutory defence provisions to the approximately 25,000 New Zealanders who could benefit from palliative care. It is not clear how many would choose to use illicit cannabis.</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.</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 person requiring palliation defends a charge.</p> <p>There may be a small cost to people requiring palliation 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 SOP 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 SOP, 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>YES</b>
<b>(b) the nature and level of regulator effort put into encouraging or securing compliance?</b>	<b>YES</b>
<p>The SOP proposes to give further guidance about the regulation-making power to prescribe minimum quality standards for products. The potential costs and benefits of the quality standards provision will be impacted by the level of compliance with the quality standards, and the nature and level of regulator effort put into encouraging or securing compliance. No, or ineffective, compliance with the quality standards may affect the quality of products, which will impact on patient safety, and impact prescriber confidence. Compliance arrangements will be considered as part of the consultation process.</p>	

## Part Three: Testing of Legislative Content

### Consistency with New Zealand's international obligations

<b>3.1. What steps have been taken to determine whether the policy to be given effect by this SOP is consistent with New Zealand's international obligations?</b>
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The change to apply the statutory defence and exception provisions to people eligible to receive palliation, rather than people with a terminal illness, is consistent with New Zealand's obligations under the United Nations' Drug Conventions.
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### Consistency with the government's Treaty of Waitangi obligations

<b>3.2. What steps have been taken to determine whether the policy to be given effect by this SOP is consistent with the principles of the Treaty of Waitangi?</b>
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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 SOP are consistent with the principles of the Treaty of Waitangi.
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### Consistency with the New Zealand Bill of Rights Act 1990

<b>3.3. Has advice been provided to the Attorney-General on whether any provisions of this SOP appear to limit any of the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990?</b>
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NO
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### Offences, penalties and court jurisdictions

<b>3.4. Does this Bill create, amend, or remove:</b>
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<b>(a) offences or penalties (including infringement offences or penalties and civil pecuniary penalty regimes)?</b>
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YES
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<b>(b) the jurisdiction of a court or tribunal (including rights to judicial review or rights of appeal)?</b>
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NO
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The exception and statutory defence for people eligible for palliation to possess and use illicit cannabis amends section 7 of the Misuse of Drugs Act.
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<b>3.4.1. Was the Ministry of Justice consulted about these provisions?</b>
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YES
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The Ministry of Justice was consulted on the policy as part of the Social Wellbeing Committee and Cabinet Legislation Committee Cabinet papers.
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### 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>
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NO
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<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 SOP, or on a draft of this SOP?</b>	<b>YES</b>
<p>The Ministry has consulted with the following agencies on the policy as part of the Cabinet Legislation Committee paper consultation: Parliamentary Counsel Office, Department of the Prime Minister and Cabinet (Policy Advisory Group), New Zealand Police, New Zealand Ministry of Justice, New Zealand Customs Service, Accident Compensation Corporation, Te Puni Kōkiri, The Treasury New Zealand, Ministry for Pacific Peoples, Oranga Tamariki, Ministry for Primary Industries, Ministry of Business, Innovation &amp; Employment, and PHARMAC.</p>	

### Other testing of proposals

<b>3.7. Have the policy details to be given effect by this SOP been otherwise tested or assessed in any way to ensure the SOP provisions are workable and complete?</b>	<b>YES</b>
<p>The workability of the exception and statutory defence provisions for people requiring palliation was tested as part of the development of the Bill. The SOP extends the group of patients covered by these provisions. The mechanism for Police to identify who is covered by the provision (certification by a doctor or nurse practitioner) is not affected by the SOP.</p> <p>The Ministry will continue to work with Police, as well as other agencies and health practitioners to develop guidelines for medical practitioners, nurse practitioners and enforcement agencies, and for people eligible to receive palliation.</p>	

## Part Four: Significant Legislative Features

### Compulsory acquisition of private property

<b>4.1. Does this SOP 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 SOP 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 SOP:</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 eligible for palliation, 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. The onus is on the person eligible for palliation to provide evidence that the exception or statutory defence applies.</p> <p>The SOP changes the eligibility criteria, so that instead of the provisions applying to a person with a terminal illness who is expected to pass away within 12 months, the provisions apply to a person eligible for palliation.</p>	

### Civil or criminal immunity

<b>4.5. Does this SOP create or amend a civil or criminal immunity for any person?</b>	<b>YES</b>
<p>The SOP creates a criminal immunity for people eligible for palliation who possess and use illicit cannabis.</p>	



## Significant decision-making powers

<b>4.6. Does this SOP 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 SOP 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 SOP create or amend any other powers to make delegated legislation?</b>	<b>YES</b>
<p>The Bill enables regulations to be made to set quality standards for cultivation and production of medicinal cannabis.</p> <p>This SOP proposes giving further guidance on this regulation-making power. The proposed amendments:</p> <ul style="list-style-type: none"><li>• allow minimum quality standards to be set for all stages of production and for all relevant products; and</li><li>• require the Minister of Health to recommend the making of regulations setting minimum standards for products containing cannabis no later than 1 year after the date on which the Bill comes into force</li></ul>	

## 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>