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**Medicinal cannabis
Scheme**

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Overview of medicinal cannabis scheme

- The scheme aims to provide a supply of quality medicinal cannabis products, where a doctor determines a patient could benefit
- The scheme will:
 - enable domestic cultivation and manufacture
 - allow import of cannabis plant material and manufactured cannabis medicines
- The scheme has three main elements:
 - a licensing regime
 - introduction of quality standards for medicinal cannabis products
 - establishment of a medicinal cannabis agency



Official RELEASER OVERVIEW OF MEDICINAL CANNABIS SCHEME (continued)

- Scheme covers all cannabis products used for a therapeutic purpose, including:
- products consented for distribution by Medsafe
 - unconsented cannabis based products
- Medicinal cannabis products will have to meet quality standards, including:
- composition true to label
 - contaminants are limited
- Access to medicinal cannabis will be via prescription

Licensing

- Each stage of producing and supplying medicinal cannabis products will require a licence
- This includes cultivation, processing, manufacture, import, export, and distribution
- Licence will set conditions that must be met, including quality standards

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Agency

- A medicinal cannabis agency to oversee the scheme will be set up
- The agency is required to comply with our international obligations
- The agency will:
 - oversee licensing
 - monitor compliance
 - collect and report on data to meet our international obligations
 - develop or endorse guidelines for medicinal cannabis products

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Interim Advisory Committee

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- We are looking to improve:
 - the prescribing process
 - information on medicinal cannabis available to medical practitioners
- An interim advisory committee is currently being set up
 - will include doctors, nurses, pharmacists, and consumer representatives
- The committee will:
 - review the need for Ministry pre-approval to prescribe medicinal cannabis products
 - look at information needs for clinicians

Amendment Bill

- A Misuse of Drugs (Medicinal Cannabis) Amendment Bill is being considered
 - currently at Select Committee stage
- The Amendment Bill makes three key changes:
 - removes Cannabidiol (CBD) from the list of controlled drugs
 - provides people with a terminal illness a defence to the charge of possession and use of cannabis
 - allows quality standards to be set for medicinal cannabis products
- You can make a submission on this Bill

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Feedback

- We would like your feedback on the Amendment Bill and the medicinal cannabis scheme
- You can contact Asti Laloli, Policy Advisor, by emailing asti_laloli@moh.govt.nz



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The Medicinal Cannabis Scheme

“The Scheme”

Project Charter: January 2018

Prepared by:	Veronika Munro
Date:	16.01.18
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Status:	Final Draft

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Document Control

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1.1	20 Dec 2017	Veronika Munro	Edits post "scheme" planning meeting
1.2	11 Jan 2018	Veronika Munro	Edits from EH
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Associated Documents

Document Name	Version	Release Date
Cabinet Paper		18 Dec 2017
Misuse of Drugs (Medicinal Cannabis) Amendment Bill		20 Dec 2017

1 Project Purpose and Objectives

The purpose of this work programme is to improve access to medicinal cannabis for those whose conditions may benefit through a system that is fair, quality-controlled, safe and compassionate.

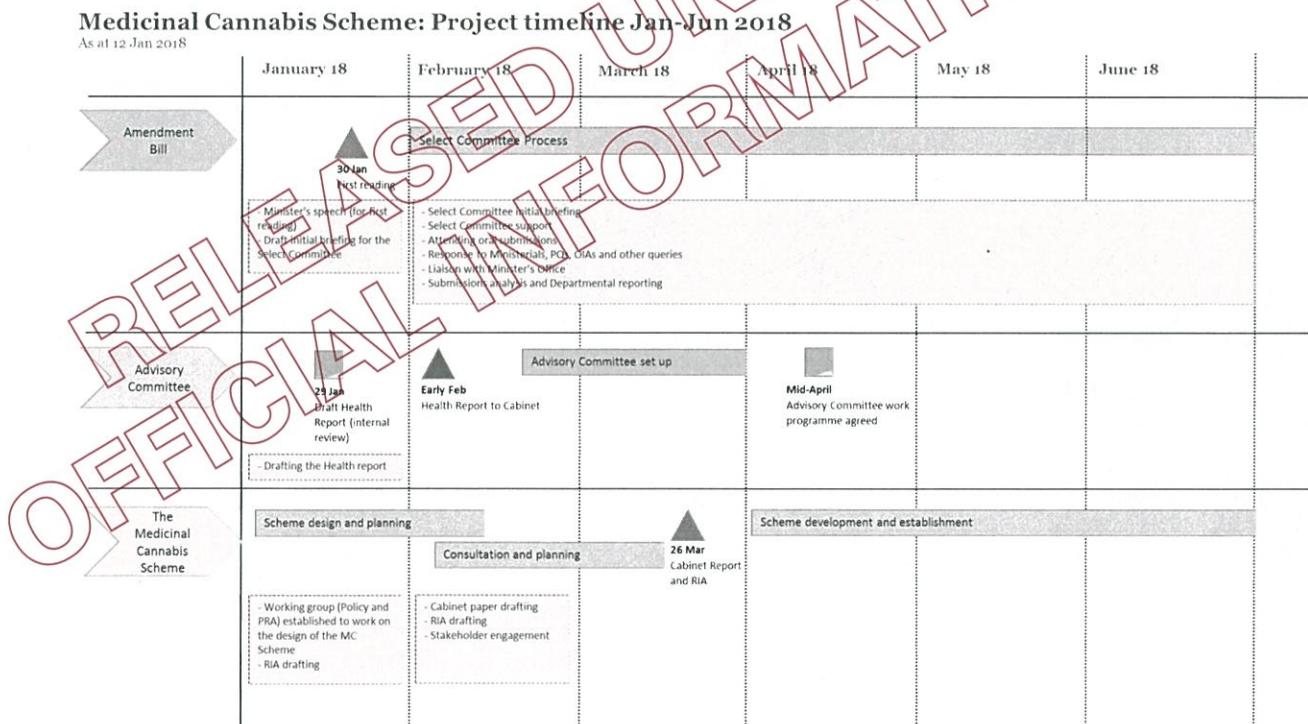
1.1 Objectives

To achieve this purpose the Ministry will:

- Assist progress of the Draft Bill through the House (including Select Committee process)
- Establish and manage an interim Advisory Committee to inform decision on medicinal cannabis (until an Agency is established), and
- Design and establish a Regulatory Agency that will implement the Scheme

2 Project Overview

The phasing and indicative timeframe for the Medicinal Cannabis Project is shown in the following object



3 Scope

There are two key components involved in the Scheme:

- Progress of the Misuse of Drugs (Medicinal Cannabis) Amendment Bill, and
- Development of a Medicinal Cannabis Scheme which will include:
 - o The establishment of an Advisory Committee, and

-
- The establishment of a Regulatory Agency

3.1 The Draft Bill

A draft Bill (Misuse of Drugs – Medicinal Cannabis – Amendment Bill) was introduced into the House on 20 December 2017. The first reading of the Bill is scheduled to take place on 30 January 2018.

The Ministry will provide support and advice to the Minister and the Select Committee through the process of taking the Bill through to its final state of enactment or dissolution.

Legislative Process	Ministry Deliverables and Milestones	Indicative timeframes
Introduction	Media and communications support Maintain Ministry website	January 2018
First reading	Minister's speech	30 January 2018
Select Committee	Officials will support the Committee Prepare initial briefing for the Committee Attend oral submissions on the Bill Response to Ministerials, PQs and other queries as required Liaison with Minister's office Analysis of submissions Department report on submissions	February – July 2018
Second reading	Minister's speech	TBC
Committee of the Whole House	Clause by clause analysis	TBC
Third reading	Minister's speech	TBC
Draft Bill passed into legislation by Royal Assent (pre-supposes that the Bill proceeds through all stages successfully)		TBC

3.2 Medicinal Cannabis Scheme

Ministry Deliverables and Milestones	Indicative timeframes
Working group established	20 January 2018
Design meeting	30 January 2018
Cabinet report back	26 March 2018

Ministry Deliverables and Milestones	Indicative timeframes
Establishment of a Regulatory Agency to oversee regulation and quality assurance of medicinal cannabis in New Zealand	TBC

3.2.1 Advisory Committee

Ministry Deliverables and Milestones	Indicative timeframes
Health report (Committee purpose, proposed structure, proposed selection process or options)	Early Feb
Committee established to provide advice on the Scheme as an interim measure while the Regulatory Agency is being established	February – March 2018
Work programme to be developed and implemented	TBC
Review of Committee post establishment of the Regulatory Body	TBC

4 Project Team

4.1 Estimated business resources

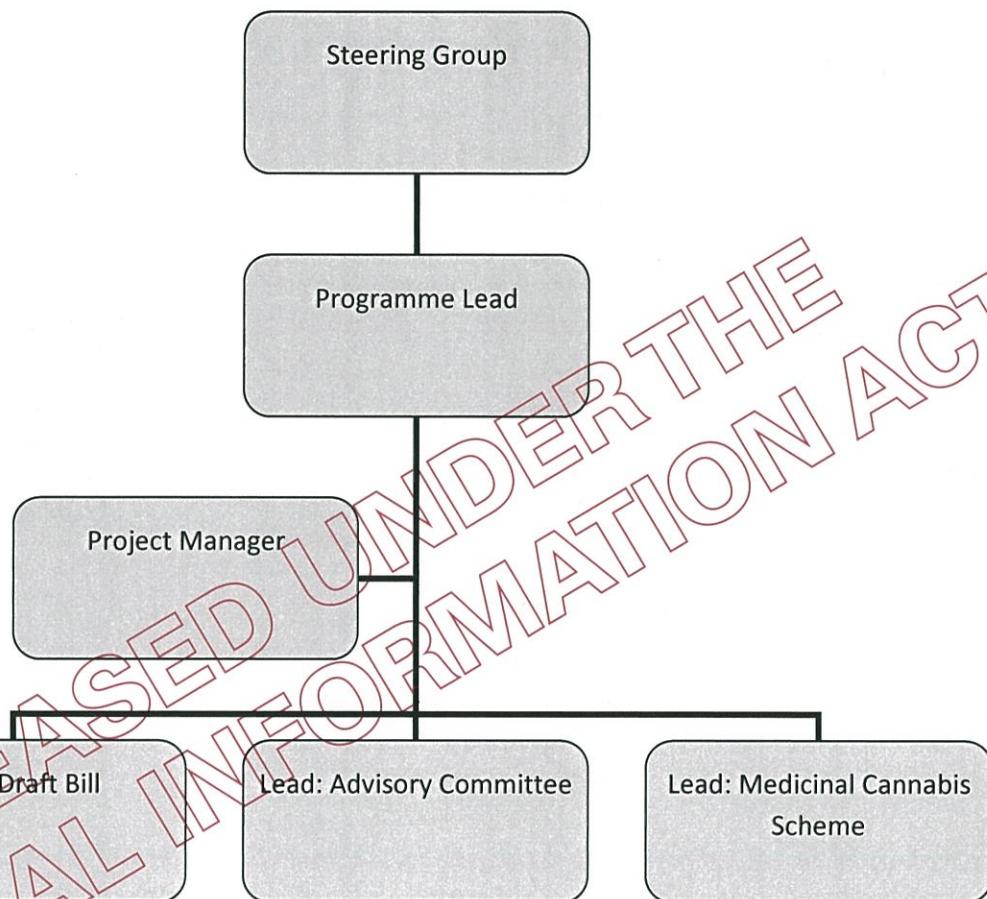
The project team is made up of the resources set out in the table below. This team is support by the NDF-TP Steering Group.

Project Roles	MOH resource	Accountabilities
Steering Group	Stewart Jessamine Hannah Cameron: Deputy Chief Policy Officer Chris James: General Manager (PRA Medsafe) Phil Knipe: Chief Legal Advisor Andrew Simpson: Chief Medical Officer	Governance oversight Resource provision Officials supporting the Select Committee process Executive accountability Health spokesperson/s
Programme Lead	Emma Hindson/ Haley Ataera	Policy oversight Programme and resources management
Project Manager	Veronika Munro	Project planning, tracking, monitoring and reporting Stakeholder engagement and consultation Risks and issues management and reporting Links and dependencies tracking

Project Roles	MOH resource	Accountabilities
		Quality assurance processes and systems Machinery of Government processes and systems
Lead: Draft Bill	Policy/ Legal	Lead work related to supporting the Bill through the Parliamentary process including Select Committee, Readings and Committee of the Whole House
Lead: Advisory Committee	Regulatory/ Policy	Oversee set up, work programme and reporting of the Advisory Committee
Lead: Medicinal Cannabis Scheme	Policy/ Regulatory	
Programme team (other)	Other resources will be sourced as required and in agreement with the Steering Group	

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4.2 Project Structure



5 Stakeholders

To ensure that stakeholders are engaged in a timely, effective and relevant manner, a Stakeholder Engagement Plan has been developed and is being updated as part of the project update. The key stakeholders for this project are set out in the table below. A full list of stakeholders and interested parties is available on request.

Stakeholder group	Members	Nature & level of interest
Members of Parliament	Minister of Health Associate Minister of Health Members of Parliament	The Minister of Health and Cabinet colleagues have, as policy decision makers, a high level of interest. Other Ministers and MPs can also be expected to have an interest in reflecting their own policy views and advocating on behalf of constituents

Stakeholder group	Members	Nature & level of interest
Internal stakeholders	Director-General ELT Medsafe Policy Ethics Chief Medical Officer Office of the Chief Nurse Health Legal	Staff with a regulatory, policy or operational interest in any aspect regarding regulation of medicinal cannabis (including licencing and prescribing etc) will wish to be engaged at an early stage. They have a high interest in the project in relation to those aspects which relate to their role in the Ministry
Government agencies	Department of Prime Minister and Cabinet (DPMC) Treasury Ministry of Justice NZ Police Ministry for Children Oranga Tamariki Ministry of Business, Innovation and Employment Parliamentary Counsel Office NZ Customs Ministry for Primary Industry (Food Safety Authority) Ministry for the Environment (Environmental Protection Agency) ACC Te Puni Kokiri Health Quality and Safety Commission Office of the Ombudsman Environmental Science and Research NZ Trade and Enterprise NZ Commerce Commission	Government agencies will be interested in ensuring proposals are well reasoned and sound; and/or have an interest in ensuring that the respective roles of co-operating agencies are clear and dovetail neatly with others.
Industry (growers, manufacturers, suppliers, wholesalers and retailers etc for all product types)	Hemp Association of New Zealand Others TBC	These industry bodies/ organisations will be directly impacted by regulation and have a high interest in ensuring that compliance and regulatory costs are minimised. They will therefore expect early engagement.
Healthcare providers who will be directly impacted by the regulatory reform, particularly those relating to controlled activities	District Health Boards Individual health providers NZMA Council of Medical Colleges	Providers will have a high level of interest in relation to specific aspects such as prescribing rights but, with the exception of policy in relation to access to unapproved products, a

Stakeholder group	Members	Nature & level of interest
such as prescribing	Hospice NZ/ Palliative care sector GPNZ Te Ora Nga Ngaru Hauora o Aotearoa Nursing Council Medical Council Dental Council	lower level of general interest in relation to product regulation.
Pharmacy groups who will be directly impacted by	Pharmacy Guild Pharmaceutical Society Pharmacy Council NZ Hospital Pharmacists Association Green Cross Pharmac	Pharmacy groups will have a high level of interest in those aspects of the Scheme relating to pharmacy licensing, prescribing and dispensing controls and the scheduling of medicines. They will be less interested in other aspects of the reform.
Consumer groups with a particular interest in health	Cancer Society Women's Health Action Auckland Women's Health Council Rural Women NZ National Council of Women NZORD NZ Health Trust Grey Power Heart Foundation Arthritis Foundation Asthma and Respiratory Foundation Rare Diseases Group Epilepsy foundation	These groups may wish to have an opportunity to submit comments on the proposed scheme.
Universities and Colleges	University of Otago Centre for Adverse Reactions Monitoring (CARM) NZ Poisons Centre College of GPs College of Anaesthetists College of Surgeons College of Obstetricians and Gynaecologists College of Ophthalmologists College of Midwives Nursing College	These organisations may wish to have an opportunity to submit comments but will not expect to be engaged at an earlier stage.

Stakeholder group	Members	Nature & level of interest
Research bodies	Health Research Council Centre for Public Health Research (Massey University) Heart Research Institute Medical Research Institute of NZ	Interest in impact on clinical trials and impact on research controls. Will wish to have an opportunity to submit on the proposed scheme.
Media, including the specialist health publications	General Media NZ Doctor Pharmacy Today	Media, particularly specialist health publications, will be interested in regular progress updates and commenting on proposals.
International organisations	World Health Organisation World Trade Organisation European Union TGA Health Canada MHRA Regulators that Medsafe has an information sharing agreement with	These organisations may have an interest in being informed of the Scheme but will not wish to be engaged in the development of reform proposals

6 Benefits and Impacts

6.1 Passing of the Misuse of Drugs (Medicinal Cannabis) Amendment Bill

This change to legislation will benefit the terminally ill who use, or intend to use, illicit cannabis products through the introduction of an exception and statutory defence allowing them to possess and use illicit cannabis without fear of prosecution.

There may be resource impacts on:

- NZ Police in undertaking an investigation to determine whether or not a person holds a valid defence at a point in time
- Court resources in processing a case where a terminally ill person defends a charge, and
- Minor costs to terminally ill persons in obtaining evidence that they hold a valid defence.

6.2 Establishment of the Medicinal Cannabis Scheme

This will benefit New Zealanders by enabling access to medicinal products that are quality assured and accessible to patients who will benefit from the use of such products as part of their treatment programme.

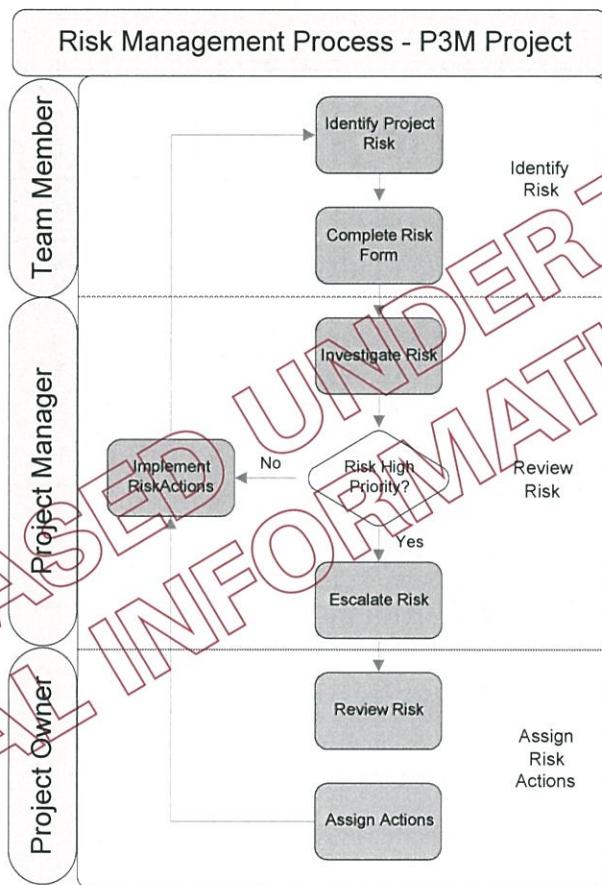
Further benefits and impacts will be considered in the March 2018 report to Cabinet, which will include a full Regulatory Impact Assessment.

7 Project Considerations

7.1 Risks

This project will manage risks as per the Ministry risk management framework, set out in the diagram below.

The



Risks for this project will be documented in the Ministry's Risk Register which is maintained by the Risk and Assurance team. Management of key risks will be reported on to the Steering Group as appropriate.

7.2 Issues

Issues for this project are documented in the project's Issues Register which is maintained by the Programme Manager. Management of key issues will be monitored and reported to the Steering Group as appropriate.

7.3 Links and Dependencies

The table below identifies the most significant links and dependencies. A full list of links and dependencies will be maintained by the Project Manager, and updated regularly as the programme progresses.

The following projects all sit within the wider Alcohol and Drug Policy work programme (to be confirmed with the Minister). These will be managed through the strategic oversight of these and other work within the Alcohol and Drug Policy programme.

- Therapeutic Products Regime
- Misuse of Drugs Regulatory review
- Utensils
- Hemp as Food
- Referendum on recreational cannabis
- National drug policy
- Advertising

7.4 Quality Control

Quality control for the deliverables for this project will be consistent with the Ministry's commissioning and sign off processes. All documents, at a minimum, will be signed off by the Programme Lead.

7.5 Assumptions

Success of this project is based on the following assumptions:

- The scope and timing of the project does not change significantly
- Sufficient resources (capacity and capability) are available to complete necessary work within the timeframes
- There are no political barriers to completing the work (such as changing priorities for Government)

7.6 Constraints/ Limitations

Success of this project may be constrained by:

- Loss of staff, particularly those with significant knowledge/ expertise required for the project
- Unexpected disruptions to business continuity, such as natural disaster or technology failure
- Changes to Government priorities
- Public opposition to the Scheme

These constraints will be managed through the risk register.

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8 Project Charter Adoption

This Project Charter is Approved / Not approved

Steering Group Chair

Signature (Stewart Jessamine)

Date:

Programme Lead (Emma Hindson)

Signature:

Date:

Project Manager (Veronika Munro)

Signature:

Date:

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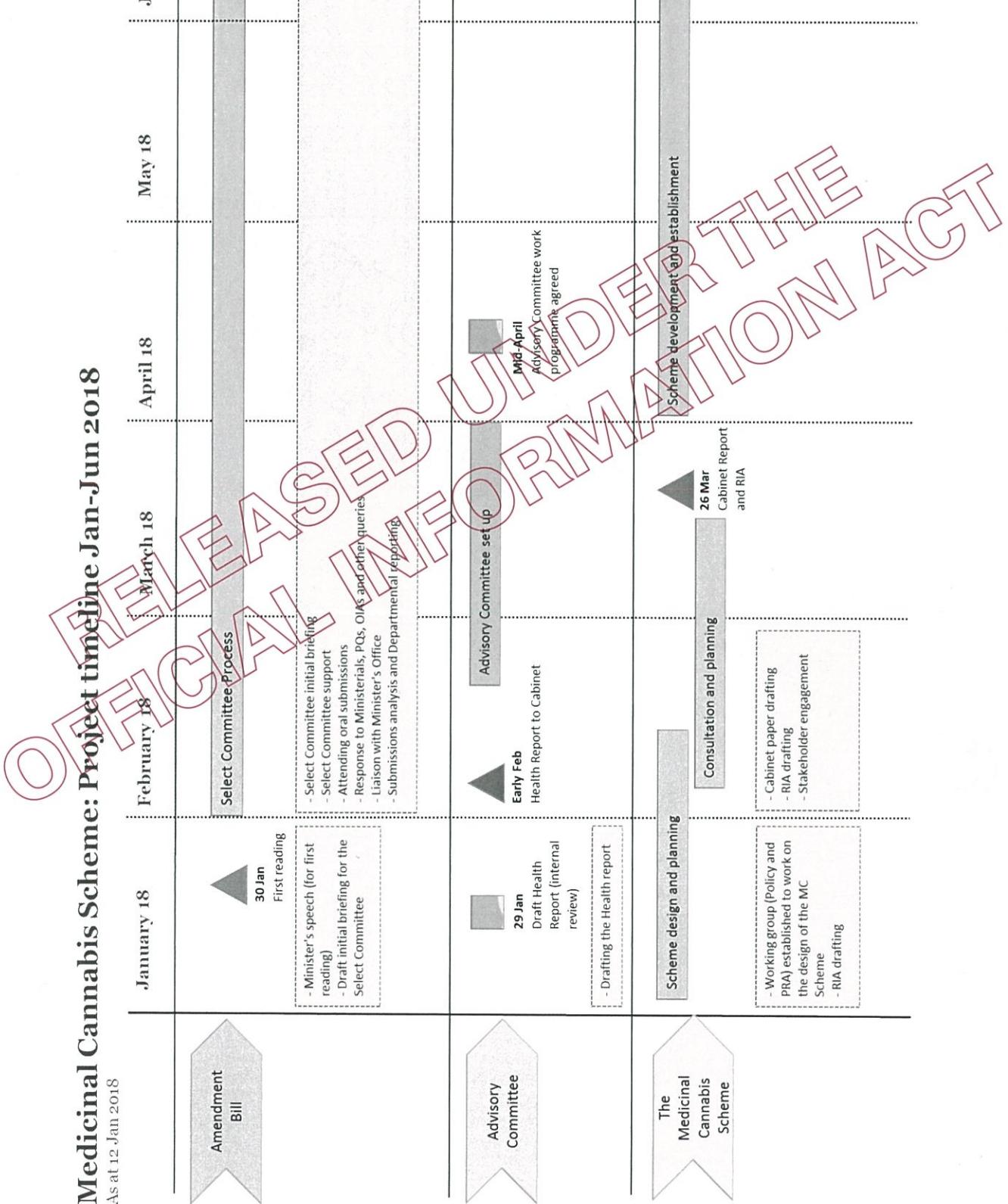
Appendix One: Indicative Timeline

	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	
Draft Bill	First reading	Select Committee																							
Advisory Committee	Health report		Appointments and First Meeting																						
Regulatory Agency	Design and planning for submission to the Minister		Budget/funding decisions																						

Indicative timeline of the development and establishment of the agency

Agency operational

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4 April 2018

Ms Louisa Wall
Chairperson
Health Committee
Parliament Buildings
Wellington

Dear Ms Wall

Misuse of Drugs (Medicinal Cannabis) Amendment Bill – initial briefing

This paper briefs the Health Committee on key aspects of the Misuse of Drugs (Medicinal Cannabis) Amendment Bill (the Bill), and provides relevant background and contextual information to support the Committee's consideration of the Bill.

This briefing includes information on:

- current access to medicinal cannabis products
- the key provisions in the Bill
- the medicinal cannabis scheme
- the interim advisory committee.

Current access to medicinal cannabis products

Currently, medicinal cannabis products are available on prescription for any medical condition. There is a lack of affordable products made to a suitable quality standard available in New Zealand.

The current evidence base for medicinal cannabis is incomplete, but developing, and medical practitioners are still determining the appropriate place for cannabis products in treatment plans (further detail is provided in Appendix A). In addition, the process of determining the safety and efficacy of a medicinal cannabis product, and then sourcing and supplying it takes time. This can be a burden on health practitioners, and a barrier to prescribing.

A readily available supply of quality products is required, so that where a health practitioner determines that a patient can benefit from medicinal cannabis, they have quality products available to prescribe with confidence.

Overview of medicinal cannabis products

Currently, medicinal cannabis products supplied on prescription come under these categories:

- *Consented cannabis based medicines*: a product with consent for distribution that has been reviewed and approved by Medsafe. Its risk/benefit profile has been assessed, based on clinical trial data, and it meets the quality and efficacy standards required. Sativex (a treatment for spasticity associated with multiple sclerosis) is currently the only consented cannabis based medicine in New Zealand. It can be prescribed for other indications with Ministry of Health approval.
- *Unconsented medicinal cannabis products*: a product that does not have consent for distribution is not required to meet any specified quality standards. The product can still be prescribed, but the prescriber must determine whether it is of acceptable quality and has sufficient evidence of efficacy. Ministry of Health approval is currently required before unconsented cannabis medicines can be prescribed.

Currently, all cannabis products are controlled drugs, regulated under the Misuse of Drugs Act 1975 (the Act). This includes Cannabidiol (CBD) and Tetrahydrocannabinol (THC), the substances in cannabis that generate the most interest in terms of potential therapeutic value. CBD has little or no psychoactive properties, whereas THC has a psychoactive effect.

Cannabis based products used for a therapeutic purpose are also regulated under the Medicines Act 1981 (Medicines Act) and the Medicines Regulations 1984. CBD and THC are classified as prescription medicines.

Despite a legal pathway, equitable access to affordable medicinal cannabis products remains problematic

Barriers to access include:

- **A reluctance to prescribe**: the medical model instils a sense of caution towards new products where evidence of efficacy is limited and side-effects uncertain, over established products with known efficacy and clinical knowledge of side-effects.
- **Accessing suitable products**: there is a limited range of products available that are made to quality standards, and strict controls around the import and export of cannabis products internationally. Sativex is available via pharmacies from a New Zealand distributor. Also, there is one wholesaler (based in Christchurch) who is stocking three varieties of unconsented Tilray (a Canadian medicinal cannabis manufacturer) medicinal cannabis products, which are made to an appropriate quality standard.
- **Cost**: Sativex costs \$1000 to \$1600 per month, depending on dose. The cost of the equivalent Tilray product is expected to be around half of Sativex. Cannimed

(another Canadian manufacturer who produces quality product) products are reportedly cheaper than Tilray, but none have been imported yet. No cannabis product is subsidised by PHARMAC.

Key provisions in the Bill

The introduction of the Bill met the Government's 100-day commitment to introduce legislation to improve access to medical cannabis.

The Bill will:

- provide an exception to the offence, and a defence to the charge of possessing and using illicit cannabis for people who have a terminal illness
- allow Government to make regulations to set quality standards for medicinal cannabis products, and
- remove CBD from the Misuse of Drugs Act, so that it is no longer a controlled drug.

The Bill is a key component in establishing a Medicinal Cannabis Scheme (the Scheme). The Scheme aims to provide a greater supply of quality medicinal cannabis products by enabling domestic cultivation and manufacture. The Scheme is described in further detail on page 10.

Statutory defence and exception for the terminally ill

The Scheme will take time to develop and implement, and we know that some people with a terminal illness are currently using illicit cannabis (that is cannabis that is for recreational use or self-medication, and is not prescribed).

The Bill provides an exception for people who have a terminal illness, and who hold evidence from their doctor of that illness. This means they will not be committing an offence in possessing or using cannabis, or possessing a cannabis utensil. If they can produce evidence at the time of questioning, they will not be prosecuted by the Police.

The Bill also provides a defence to a charge of using and possessing cannabis, or a cannabis utensil, for people who have been diagnosed with a terminal illness. If they do not have a doctor's certificate at the time of questioning, but can produce evidence of their terminal illness in Court, they will have a defence against conviction.

The effect of these provisions will be that the terminally ill will be able to use cannabis without the fear of criminal conviction. These provisions will apply to people of any age who are reasonably expected to pass away within 12 months. This is a compassionate approach for this particular group of people, where the usual concerns around product safety, quality, efficacy, and long-term risks are different.

Issues likely to be raised by submitters

We anticipate that submitters will raise some concerns around the scope of this provision of the Bill.

- *Supplying cannabis to a person with a terminal illness:* although we acknowledge that terminally ill people are likely to rely on family, whānau, and friends to source

illicit cannabis for them, the statutory defence and exception is not extended to cover supply. This provision is intended as a compassionate measure until the Scheme is established.

Supply is a much more serious offence than possession and use, and has much higher penalties. Terminally ill people have a range of support networks, and it is difficult to tightly define who the statutory defence and exception should cover for supply without introducing a risk of unscrupulous suppliers attempting to use this provision as a defence.

- *People with chronic pain:* the statutory defence and exception does not include people with chronic pain. Chronic pain is difficult to define, subjective, and would potentially cover a large patient group. According to the New Zealand Health Survey (2016/17), 20 percent of adults experience chronic pain (self-identified), which is defined as pain present almost every day, and has lasted (or is expected to last) more than six months.

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 can be prescribed a cannabis product under the current legal pathway if their medical practitioner supports its use for that individual. The Scheme will aim to make quality products accessed via prescription more readily available.

Quality standards

The majority of medicinal cannabis products that are likely to be available as part of the Scheme will be unconsented. We want to ensure that products on the market are made to a standard that allows them to be prescribed with confidence.

The Bill introduces a regulation-making power that allows quality standards to be set for products supplied under the Scheme. Without the provision in the Bill, there is no ability for the Scheme to require that products meet a quality standard.

Quality standards will provide practitioners with assurance that products supplied under the Scheme have known composition and limited contaminants (such as pesticides and heavy metals). The overall standard required is not expected to be equivalent to that required for a medicine. For example, manufacturers can, but may not be required to, provide clinical trial data for their products. The standards are likely to cover the manufacturing process, and the quality of the end product. The standards will apply to all products, both produced domestically and imported.

The setting of quality standards will be led by the Ministry of Health, as part of the establishment of the Scheme. This work will be informed by the approach taken in other jurisdictions, expert technical advice, and stakeholders.

Descheduling of CBD

The Bill will deschedule CBD so it is no longer a controlled drug, in response to the advice of the Expert Advisory Committee on Drugs (the Committee who provides expert advice to the Minister of Health on drug classification issues).

The Committee advised that CBD has potential therapeutic value and little or no psychoactive properties, and it would support descheduling CBD as a controlled drug. Naturally-derived CBD products from the cannabis plant are very likely to contain small amounts of other cannabinoids, including THC which at such low levels is unlikely to have a psychoactive effect. The Committee considered an allowance of two percent of other cannabinoids found in cannabis would be appropriate for CBD products. This two percent allowance aligns with the Australian scheduling of CBD. Further information is provided in Appendix B.

The Regulations were amended last year to remove a number of controlled drug restrictions for the import and prescribing of CBD products. However, it was not possible to remove all controlled drug restrictions for CBD by Regulations. The Amendment Bill will declassify CBD and CBD products, with less than two percent of other cannabinoids.

Medicinal Cannabis Scheme

A Scheme is being established to provide a supply of quality medicinal cannabis products. It will cover all cannabis products used for a therapeutic use.

A doctor's prescription will continue to be required for anyone to access medicinal cannabis, as THC and CBD are prescription medicines. We will provide guidance to health practitioners on how to identify products that meet the required quality standards and on the prescribing process. The scheme will not enable grow-your-own cannabis for your own medicinal purposes.

Framework of the Scheme

The Scheme has three main elements: a licensing regime; the introduction of quality standards for products; and the establishment of a medicinal cannabis agency to oversee the licensing regime and setting of quality standards.

All stages of the process of producing medicinal cannabis products, including cultivation, processing, manufacture, import, export, and distribution will require a licence. The licences will set conditions that must be met.

The Scheme will require that products supplied in New Zealand, including those imported and produced domestically, meet the quality standards set by the Regulations. Manufacturers and importers will have to show that the composition is true to label, and products are free from contaminants.

A government agency will be established to oversee the cultivation and manufacture of cannabis produced domestically. This is to comply with our international obligations under the United Nations Single Convention on Narcotic Drugs 1961 (the Single Convention). The Single Convention requires a government agency to license cultivation of medicinal cannabis.

Our approach to regulating medicinal cannabis under the Scheme is similar to Australia, the Netherlands, and Israel. All three countries have established a licensing regime, and an oversight agency to comply with the Single Convention. Further information on approaches to regulating medicinal cannabis is provided in Appendix C.

Interim Advisory Committee

A Medicinal Cannabis Advisory Committee (the Committee) is being established to bring together experts (such as clinicians and pharmacists), consumers and others. The Committee will consider the current prescribing process for medicinal cannabis products and information needs for clinicians.

The Committee will be a valuable way to engage with health practitioners and other interested parties to gain a fuller understanding of concerns, information needs and process issues.

Yours sincerely

Hannah Cameron
Deputy Chief Policy Officer
Strategy and Policy
Ministry of Health

Appendix A: Evidence for medicinal cannabis

There is emerging, but incomplete, evidence for the medicinal use of cannabis. Research suggests that specific cannabis formulations may be useful for some patients, however there is a lack of evidence to show that medicinal cannabis is more effective than established medicines.

A 2017 review of the evidence by an expert US Committee concluded that there was substantial evidence that cannabis or cannabinoids resulted in improvements over placebo for these conditions: chronic pain; multiple sclerosis spasticity; and nausea and vomiting due to chemotherapy.

However, this report notes that the majority of the studies evaluated nabiximols (i.e. Sativex). Many of the medicinal cannabis products currently available on the United States market (such as topical forms and edibles) bear little resemblance to the products researched in those studies. More research is needed on the impact of commonly used and commercially available products.

The US Committee also noted an association between cannabis use and the development of schizophrenia and other psychoses, with the most frequent users having the greatest risk. The prevalence of cannabis use among people with schizophrenia is generally higher than among the general population.

The Australian Therapeutic Goods Administration (TGA) recently released a set of guidance documents on the use of medicinal cannabis. The guidance notes that most people who seek medicinal cannabis do so for pain. The guidance notes that there is no scientific data to support medicinal cannabis for chronic nociceptive pain (caused by body tissue damage), or for chronic neuropathic pain (caused by nerve damage). Medicinal cannabis use may expose the patient to life-long use of the product, and there is no robust data on the consequences of such use. The guidance recommends caution when considering prescribing medicinal cannabis products for chronic non-cancer pain.

Appendix B: Further information on Cannabidiol

Cannabidiol (CBD), one of the cannabinoids found in cannabis, is a controlled drug regulated under the Act. CBD has little or no psychoactive properties, few adverse effects have been recorded from its use, and it may have therapeutic properties.

The Expert Advisory Committee on Drugs (EACD), a statutory committee that considers drug classification issues, advised it would support descheduling CBD as a controlled drug. This would mean that it is a prescription medicine only. The EACD found that, based on the low risk of CBD and its potential therapeutic value, the proposed change would be reasonable.

The EACD considered that an allowance of two percent of other cannabinoids found in cannabis, such as THC, would be appropriate. THC at such a low level would be unlikely to lead to diversion of products for recreational use, due to the high cost of the quality products.

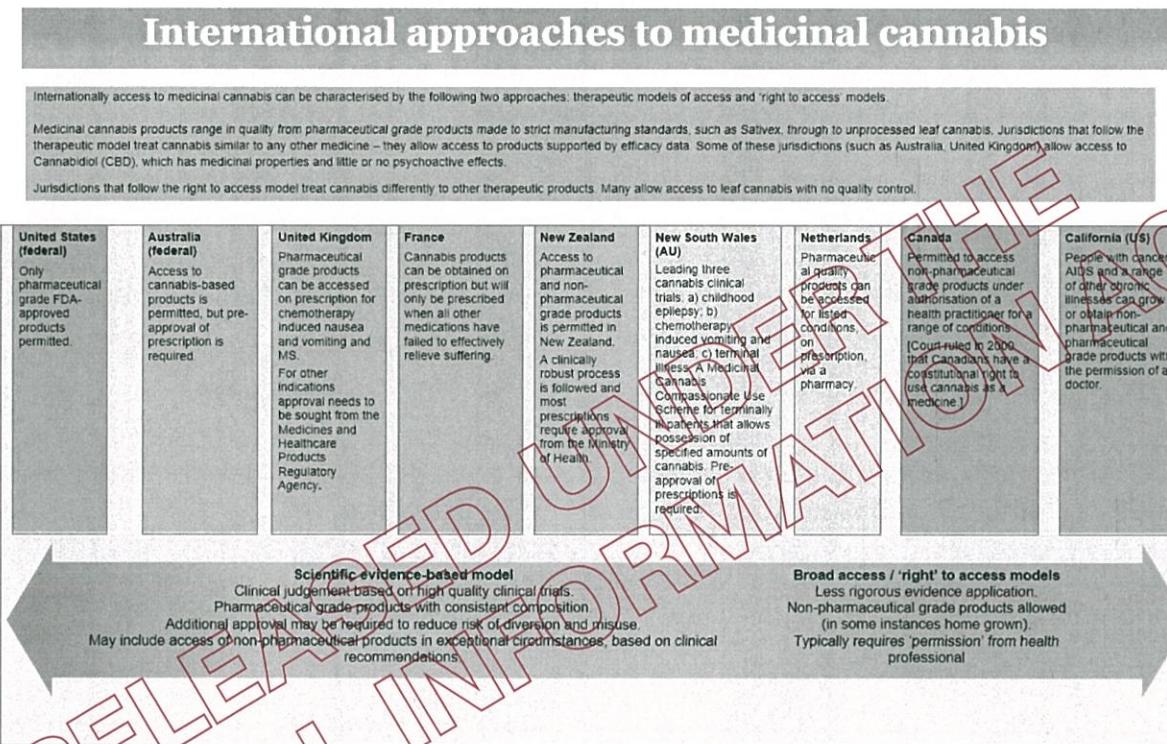
In response to the EACD's advice, the Regulations were amended to remove a number of controlled drug restrictions for the import and prescribing of CBD products. This included the requirement for Ministerial approval to prescribe; the requirement for an import licence; the requirement to be prescribed on a triplicate form; the requirement to be stored in a safe; and the records and stocktaking requirements. The period of supply was extended from one month to three. This aligned most of the CBD requirements with those of prescription medicines.

It was not possible to remove all controlled drug restrictions for CBD via the amended regulations. The penalty provisions for possessing and supplying CBD, other than pursuant to a licence or prescription, are set out in the Act and are significantly higher than for prescription medicines. The amendments to the Regulations were an interim measure until the next available opportunity to amend the Act. The Amendment Bill will declassify CBD and CBD products, bringing all requirements in line with other prescription medicines.

This change will bring New Zealand into line with other countries such as Australia, who made a similar change in 2015. The World Health Organization late last year noted that CBD could have therapeutic value and did not carry any addiction risks.

Appendix C: International regulation of medicinal cannabis

International regulation of cannabis falls on a spectrum. On one side, regulation follows a scientific evidence-based model, under which medicinal cannabis is treated the same as any other medicine. On the other end of the spectrum, there is a compassionate “right to access” approach, which broadens access to cannabis products due to social demand, rather than clinical efficacy.



Australia

Medicinal cannabis is available under the Authorised Prescriber Scheme (APS) and Special Access Scheme (SAS), and can be accessed through clinical trials. Some states also require State-level approval.¹

APS allows a doctor, who has been approved by the Therapeutic Goods Association (TGA), to prescribe cannabis to a specified group of patients.² SAS allows the import or supply of medicinal cannabis for a single patient on a case by case basis.

Australia has established a regulatory framework for domestic cultivation. This includes establishing the Office of Drug Control to oversee cultivation, manufacture, import/export of medicinal cannabis and other controlled drugs via a licensing scheme. We understand this allows Australia to meet their international obligations under the Single Convention. Cultivation and manufacture is permitted under licence. Medicinal cannabis products must be manufactured to Good Manufacturing Practice (GMP) (the international standard for pharmaceutical products).

¹ Australian Government, Department of Health, Therapeutic Goods Administration, Access to medicinal cannabis products, accessed at <https://www.tga.gov.au/access-medicinal-cannabis-products>.

² Australian Government, Department of Health, Therapeutic Goods Administration, Authorised prescribers, accessed at <https://www.tga.gov.au/form/authorised-prescribers>.

The TGA has issued prescribing guidance for medicinal cannabis.

Netherlands

The Netherlands allows access to pharmaceutical grade cannabis through doctor prescription.

The Netherlands have a centralised Office of Medicinal Cannabis (the OMC) who take control of the cannabis product in line with the United Nations conventions requirements. The OMC has a monopoly on supplying medicinal cannabis to pharmacies, and on its import and export. The OMC is responsible for overseeing all cultivation and distribution of all medicinal cannabis.

Bedrocan is the sole supplier of medicinal cannabis. Bedrocan granulated plant products are made to GMP standard, and are administered by an inhaler.

The cannabis is supplied to the OMC who then supplies it to pharmacies. Prescriptions are then dispensed by pharmacies, similar to any other medicine.

Israel

Israel allows access to medicinal cannabis under a 'medicalisation' model. They are moving to bring cannabis as close to a medicine as possible.

Israel have a list of conditions for which medicinal cannabis can be prescribed. Standard treatments must be tried first. Standardised product is dispensed by pharmacies.

Israel has a government agency for cannabis, the Israel Medicinal Cannabis Agency, within the Ministry of Health. The Agency has developed quality assurance standards for all components of the supply chain (cultivation, manufacture, distribution, and security). They have also developed clinical guidelines known as the "Green Book".

International industry

Some key players in the medicinal cannabis industry internationally are G.W. Pharmaceuticals (who produce Sativex); Bedrocan (the Netherlands state supplier of medicinal cannabis); Tilray; and Cannimed (both Canadian producers). All these companies produce medicinal cannabis products to a quality standard. Sativex, and three types of Tilray products, are stocked in New Zealand.

Security classification: In-Confidence

Quill record number: H201800460

File number: AD62-14-18

Action required by: 7 February 2018

Meeting with Worik Stanton – medicinal cannabis talking points

To: Hon Dr David Clark, Minister of Health

Purpose

This briefing provides you with information for a meeting with Worik Stanton, on 9 February 2018, at 12pm. The meeting is for 30 minutes and will cover progress on medicinal cannabis reform.

Talking points

Misuse of Drugs (Medicinal Cannabis) Bill

1. The changes proposed in the Misuse of Drugs (Medicinal Cannabis) Bill are intended to strengthen the existing therapeutic model and improve access to quality medicinal cannabis products.
2. The Bill includes a regulation-making power to enable quality standards to be set for medicinal cannabis products available on prescription, and deschedules cannabidiol as a controlled drug.
3. The Bill also provides an exception and a statutory defence for the possession and use of illicit cannabis for terminally ill people who have less than 12 months to live. This is a compassionate approach that acknowledges that some terminally ill people are currently choosing to use illicit cannabis to relieve their symptoms.
4. The Misuse of Drugs (Medicinal Cannabis) Bill had its First Reading in Parliament on 30 January and has been referred to the Health Committee for consideration.

Medicinal Cannabis Scheme

5. The Government is developing a medicinal cannabis scheme to improve access to quality medicinal cannabis on prescription. The Scheme will include enabling domestic cultivation and manufacture and will result in a greater supply of quality medicinal cannabis.
6. Under the medicinal cannabis scheme, manufacturers will have to show that the composition is true to label, and products are free from contaminants.
7. New Zealand has international obligations to meet under United Nations drug conventions. The convention requires a government agency to oversee the cultivation and manufacture of cannabis produced domestically. This agency will be within the Ministry of Health.
8. The development of the scheme and agency will be a key focus throughout 2018.

Medicinal Cannabis Advisory Committee

9. A medicinal cannabis advisory committee will review the requirement for approval from the Ministry of Health before health practitioners can prescribe cannabis products, and will look at information needs for patients and health practitioners. This advisory committee will include doctors, nurses, pharmacists, and consumer representatives.
10. The Committee is currently being established.

END.

Contacts:	Hannah Cameron, Deputy Chief Policy Officer, Strategy and Policy	021 783 574
	Sharon Woollaston, Senior Policy Analyst, Strategy and Policy	04 496 2028

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Security classification: In-Confidence

Quill record number: H201800462

File number: AD62-14-18

Action required by: 7 February 2018

Meeting with Dr Geoff Noller – Medicinal Cannabis

To: Hon Dr David Clark, Minister of Health

Purpose

This briefing provides you with information for a meeting with Dr Geoff Noller, on 9 February 2018, at 2pm at your electorate office. The meeting is for 30 minutes and will cover medicinal cannabis policy.

Background

1. Dr Geoff Noller is a medical anthropologist and independent researcher with an interest in drug policy and cannabis use. Dr Noller is also a board member of NORML (National Organisation for the Reform of Marijuana Laws).

Talking points

Misuse of Drugs (Medicinal Cannabis) Bill

2. The changes proposed in the Misuse of Drugs (Medicinal Cannabis) Bill are intended to strengthen the existing therapeutic model and improve access to quality medicinal cannabis products.
3. The Bill includes a regulation-making power to enable quality standards to be set for medicinal cannabis products available on prescription, and deschedules cannabidiol as a controlled drug.
4. The Bill also provides an exception and a statutory defence for the possession and use of illicit cannabis for terminally ill people who have less than 12 months to live. This is a compassionate approach that acknowledges that some terminally ill people are currently choosing to use illicit cannabis to relieve their symptoms.
5. The Misuse of Drugs (Medicinal Cannabis) Bill had its First Reading in Parliament on 30 January and has been referred to the Health Committee for consideration.

Medicinal Cannabis Scheme

6. The Government is developing a medicinal cannabis scheme to improve access to quality medicinal cannabis on prescription. The Scheme will include enabling domestic cultivation and manufacture and will result in a greater supply of quality medicinal cannabis.
7. Under the medicinal cannabis scheme, manufacturers will have to show that the composition is true to label, and products are free from contaminants.
8. New Zealand has international obligations to meet under United Nations drug conventions. The convention requires a government agency to oversee the cultivation and manufacture of cannabis produced domestically. This agency will be within the Ministry of Health.
9. The development of the scheme and agency will be a key focus throughout 2018.

Medicinal Cannabis Advisory Committee

10. A medicinal cannabis advisory committee will review the requirement for approval from the Ministry of Health before health practitioners can prescribe cannabis products, and will look at information needs for patients and health practitioners. This advisory committee will include doctors, nurses, pharmacists, and consumer representatives.
11. The Committee is currently being established.

END.

Contacts:	Hannah Cameron, Deputy Chief Policy Officer, Strategy and Policy	021 783 574
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Security classification: In-Confidence

File number: AD62-14-18
Action required by: 30 January 2018

Speech Notes: First Reading of Misuse of Drugs (Medicinal Cannabis) Amendment Bill

To: Hon Dr David Clark, Minister of Health

Purpose

This briefing provides you with a speech for the first reading of the Misuse of Drugs (Medicinal Cannabis) Amendment Bill on 30 January 2018.

Key points

- The Misuse of Drugs (Medicinal Cannabis) Amendment Bill was introduced on 20 December 2017.
- Enclosed as Appendix One is a speech you may wish to use for the first reading to the House.

Recommendations

This report is for your information only and does not request any decisions.

Hannah Cameron
Deputy Chief Policy Officer
Strategy and Policy

Minister's signature:

Date:

Contacts:	Hannah Cameron, Deputy Chief Policy Officer, Strategy and Policy	021 783 574
	Asti Laloli, Policy Analyst, Strategy and Policy	04 816 2619

Appendix One: Speech for first reading of the Misuse of Drugs (Medicinal Cannabis) Amendment Bill

I move, that the *Misuse of Drugs (Medicinal Cannabis) Amendment Bill* be now read a first time. I nominate the Health Committee to consider the Bill. This Bill amends the Misuse of Drugs Act 1975.

Introduction

This Bill makes three key changes:

- It provides people who have a terminal illness a defence to the charge of possessing and using cannabis;
- It will allow us to make regulations to set quality standards for medicinal cannabis products; and
- It removes cannabidiol from the Misuse of Drugs Act, so that it is no longer a controlled drug.

The Bill does not make any changes to the recreational use of cannabis.

Medicinal cannabis scheme

New Zealanders can get medicinal cannabis products now on prescription, but there are few quality products available, they are expensive, and it can take weeks to import them. Medicinal cannabis products have the potential to ease suffering, and they should be easier to access.

We are developing a medicinal cannabis scheme to improve access to quality medicinal cannabis on prescription. This will include enabling domestic cultivation and manufacture. This will result in a greater supply of quality medicinal cannabis, including products made here in New Zealand.

The Bill will allow quality standards to be set for all medicinal cannabis products, whether produced domestically or imported.

Medicinal cannabis products that are not produced to a quality standard may be unsafe. We do not know the composition of these products, or their potential psychoactive effect. These products may contain contaminants, such as pesticides. Health practitioners are right to be cautious about prescribing these products.

Under the medicinal cannabis scheme, manufacturers will have to show that the composition is true to label, and products are free from contaminants.

We consider that health practitioners are best placed to decide whether a person would benefit from medicinal cannabis. This is why we will continue to require a prescription from a health practitioner to access medicinal cannabis under the scheme.

We also have international obligations to meet under United Nations drug conventions. The convention requires a government agency to oversee the cultivation and manufacture of cannabis produced domestically. This agency will be within the Ministry of Health.

We will establish a medicinal cannabis advisory committee early this year. Currently, health practitioners must get approval from the Ministry of Health before they can prescribe cannabis products. The committee will review this requirement, and will look at information needs for patients and health practitioners. This advisory committee will include doctors, nurses, pharmacists, and consumer representatives.

The development of the scheme and agency will be a key focus throughout 2018.

Statutory defence

The scheme will take time to develop and implement, and we know that some people with a terminal illness are currently using illicit cannabis. In the meantime, the Bill establishes a defence to the charge of using and possessing cannabis, or a cannabis utensil, for people who have been diagnosed with a terminal illness.

Terminally ill people are likely to rely on family, whanau, and friends to source illicit cannabis for them. We do not propose extending the statutory defence to cover the range of people who could supply cannabis to terminally ill people. This would greatly widen the scope of the defence. We want to keep the scope narrow, as it is intended as a compassionate measure until the scheme is established.

I intend to address supply through the development of the scheme, which once established, will ensure quality products are readily available.

Descheduling cannabidiol

The Bill will also remove cannabidiol from the list of controlled drugs. Cannabidiol is a substance found in cannabis that has potential therapeutic value and little or no psychoactive properties. The Bill will make it a prescription medicine, rather than a controlled drug.

The change to the legal status of cannabidiol responds to the advice of the Expert Advisory Committee on Drugs', which considers drug classification issues. They found that, based on the low risk of cannabidiol and its potential therapeutic value, the proposed change would be reasonable.

This change will bring New Zealand into line with other countries such as Australia, who made a similar change in 2015. The World Health Organization late last year noted that cannabidiol could have therapeutic value and did not carry any addiction risks.

I commend this Bill to the House.

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Security classification: In-Confidence

File number: AD62-14-2017

Action required by: 9 March 2018

Draft Cabinet Paper: Establishment of the medicinal cannabis scheme

9(2)(f)(iv)



Contacts:	Hannah Cameron, Group Manager, Regulatory Policy Strategy and Policy	021 783 574
	Chris James, Group Manager, Medsafe	04 819 6810

9(2)(f)(iv)



Hannah Cameron
Deputy Chief Policy Officer
Policy and Strategy

Minister's signature:

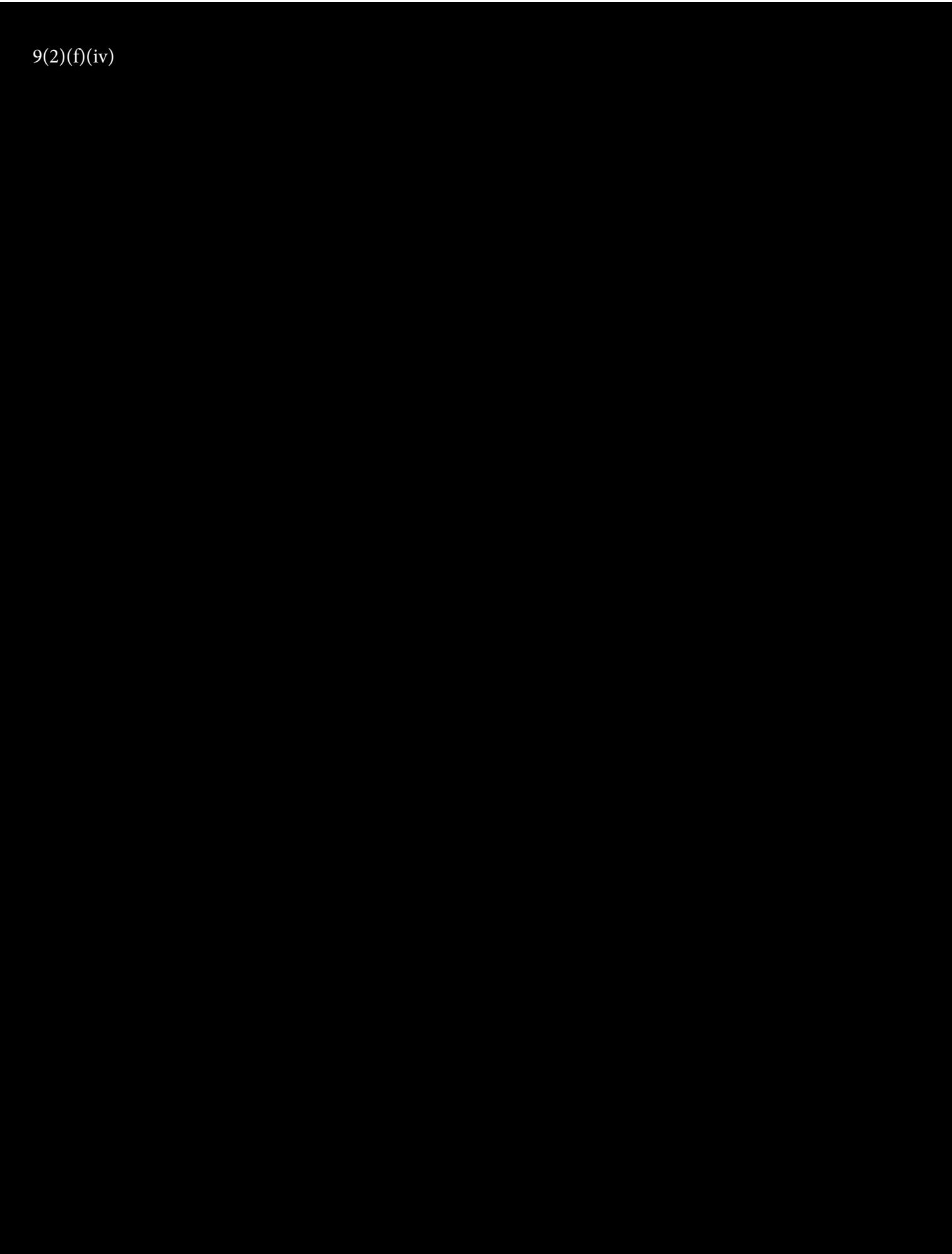
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Appendix A: International approaches to regulating cultivation of medicinal cannabis

Jurisdiction	Regulation of medicinal cannabis
Australia	Australia has established the Office of Drug Control to oversee cultivation, manufacture, import/export of medicinal cannabis and other controlled drugs via a licensing scheme. We understand this allows Australia to meet their international obligations under the Single Convention. Cultivation and manufacture is permitted under licence. Medicinal cannabis products must be manufactured to Good Manufacturing Practice (GMP).
Netherlands	The Netherlands have a centralised Office of Medicinal Cannabis (the OMC) who take control of the cannabis product in line with the United Nations conventions requirements. The OMC has a monopoly on supplying medicinal cannabis to pharmacies, and on its import and export. The OMC is responsible for overseeing all cultivation and distribution of all medicinal cannabis. Production of pharmaceutical grade product occurs OMC contracts.
Israel	Israel has a government agency for cannabis, the Israel Medicinal Cannabis Agency (IMCA), within the Ministry of Health, in line with UN convention requirements. Israel has a medicalisation model, under which the IMCA has developed quality assurance standards for all components of the supply chain.
Germany	Medical use of cannabis is permitted under legislation which came into effect March 2017. A cannabis agency has been created within the Federal Institute for Drugs and Medical Devices The agency will contract farms to grow cannabis and oversee each stage to ensure product produced is pharmaceutical grade.

The Medicinal Cannabis Scheme

The paper updates you on the work to date on the design and implementation of the Medicinal Cannabis Scheme. It outlines the priority of the different work streams and resources involved. The progress of this work is dependent on more resources becoming available through the Budget Bid. The Budget Bid decisions are due to made in May 2018.

Where key decisions need to be made an internal working paper will be developed which will identify where Ministerial feedback will be required. External consultation will be needed at various stages but will not occur without approval of the Steering Group. For each work stream a responsible team is identified.

Medicinal Cannabis Scheme Framework

A medicinal cannabis scheme is being established to increase access to quality medicinal cannabis products. The Scheme has three main elements: a licensing regime, the introduction of quality standards for the manufacture of products, and the establishment of a medicinal cannabis agency to oversee the licensing regime and setting of quality standards.

Activities to be covered under the Medicinal Cannabis Scheme:

- Growing
- Extracting/processing
- Manufacturing (to GMP or another standard)
- Importing
- Exporting
- Assessing products
- Distributing products
- Pharmacy licensing
- Access for patients via prescription
- Post-market surveillance, compliance, auditing and recalls
- International Narcotic Control Board (INCB) reporting

Not all of the above activities will require new systems to be put in place as the existing systems will be sufficient. See current situation and proposed changes for the Scheme in Appendix 1.

Work streams to develop the Scheme

The work streams to develop, design and implement the Scheme are described below. Work in these areas is underway, further details can be found in Appendix 2.

Across all streams of work

- Interface of the scheme with other legislation (Medicines/Therapeutics, Smokefree environments, Hemp Regs).
- Stakeholder engagement

As part of development of the regulations there is an expectation that public consultation will occur.

Quality standards

- Quality standards that all medicinal cannabis products will be required to meet.
- Growing standards that medicinal cannabis growers will be required to meet.

- Manufacturing standards that medicinal cannabis processors and manufacturers will be required to meet.
- Legislative options for allowing a list of products which meet the quality standards to be released (advertising)

This is a key element of the Scheme and will inform the development and options for licensing, compliance and monitoring as well as the quality standard regulation-making power in the Amendment Bill. Options for the quality standards need to achieve the stated objective of the Scheme to deliver quality products that can be prescribed with confidence. The quality standards will need to ensure composition of products is known and contaminants are minimised.

There are likely to be options around the stringency of requirements and combination of requirements for growers, manufacturers and end products. Quality requirements directly impact business' ability to enter the medicinal cannabis sector and the cost of producing product. The quality standards set will affect whether a product can undergo clinical trials to demonstrate safety and efficacy. They will also determine the international acceptability of products or active pharmaceutical ingredients for export, particularly to Europe. Quality standards and the audit, compliance and monitoring of standards also have direct resource implications for the Medicinal Cannabis Agency.

Licences and compliance activities

- Types of licences, licensing requirements and form of licences
- Transitional arrangements for existing licences and products supplied under section 29 if required
- Developing regulations to implement the licensing scheme and fees
- Compliance activities

Types of licences and licensing requirements will be informed by the decisions made for the quality standards. The interface between licences under the Scheme and licensing of the manufacturing of medicines needs to be considered. For example, if manufacturing standards are set at Good Manufacturing Practice for medicines then new licences for manufacturing will not be required.

Development of the Agency

- Budgeting and resourcing for the Agency (confirming budget, identifying required skills and experience, training needs, recruitment).
- Internal procedures for the Agency (SOPs, financial processing arrangements etc)
- Confirming proposed scheme meets international obligations
- Providing guidance information to industry and the public (growers, manufacturers, prescribers, patients).

Priority work in advance of developing the Scheme

- Secretariat support for the Medicinal Cannabis Interim Advisory Committee meeting.
- Supporting the Health Committee's consideration of the Misuse of Drugs Amendment Bill
- Review of provision for setting quality standards in the Misuse of Drugs (Medicinal Cannabis) Amendment Bill to ensure this is fit for purpose, as part of the departmental report being provided to the Select Committee.

Initial considerations

- Whether products will be assessed for meeting quality standards and how they will be assessed (by the prescriber, Agency or a third party)?
- Whether the Agency operates as a standalone team or shares resources with Medsafe?

Other work which will impact on resources available

Additional consideration also needs to be given to the hemp licensing regime. There is the possibility that the hemp licensing could be brought into the Agency's responsibilities. This would include activities such as, growing of industrial hemp, processing of industrial hemp and, in the future, producing hemp seed as food.

Changes are required to the Misuse of Drugs (Industrial Hemp) Regulations 2006 to allow hemp seed to be sold as food. As part of this, some additional changes are being proposed to clarify the regulations, for example the distinction between the Industrial Hemp regime and the Medicinal Cannabis Scheme. This work is currently underway as part of a joint project between the Ministry of Health and MPI. This work is ongoing and requires some of same expertise as is required for the Medicinal Cannabis Scheme, so this needs to be considered when allocating resource. Currently, a discussion document is being taken to Cabinet for approval to begin consultation on the proposed changes to the Misuse of Drugs (Industrial Hemp) Regulations.

Medicines Control is currently receiving a large number of queries from companies and individuals looking to apply for a licence to cultivate cannabis or hemp to set themselves up to be ready for market when the Medicinal Cannabis Scheme is running. Work is currently underway to provide guidance on the Ministry's website on the requirements of each licence as well as updating the licence applications. As this work is happening alongside the queries being received and both the queries and the guidance require the same expertise from Medicines Control, this also needs to be considered when allocating resource.

Appendix 1: Current situation and proposed changes under the Scheme

The green boxes below are ones where decisions could be made without a significant collation of information being required or where the decision is affected by the decision for another activity. The orange boxes are ones where significant research and collation of information are required before a decision can be made. This shows that the biggest decisions to be made are determining the manufacturing standard to be set and determining the product quality standard to be set and how this will be assessed. These decisions will also feed into some of the requirements for the other activities in the scheme.

Activity	Current Licensing or Assessment	Proposal for the Scheme
Growing	<ul style="list-style-type: none"> A licence to grow prohibited plants - issued by Medicines Control. 	A licence to grow prohibited plants would still be required. It could be a specific licence to grow cannabis issued by the Agency.
Extracting/processing	<ul style="list-style-type: none"> A licence to deal in controlled drug - issued by Medicines Control. A licence to manufacture medicines - issued by Medsafe (when used to make a medicine, currently can only be used for clinical trials). This would require meeting the same standards as manufacturing a medicine in line with the Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-operation Scheme for APIs. 	<p>Need to investigate and analyse different manufacturing standards which are used and whether or not they are appropriate for this scheme. A working group needs to be set up to address this question.</p> <p>If GMP were adopted, no new licences would be required. If GMP were not adopted, a licence to manufacture products could be issued under the Misuse of Drugs Act 1975.</p>
Manufacturing	<ul style="list-style-type: none"> A licence to deal in controlled drugs - issued by Medicines Control. A licence to manufacture medicines - issued by Medsafe (currently can only be used for clinical trials). 	<p>Need to investigate and analyse different manufacturing standards which are used and whether or not they are appropriate for this scheme. A working group needs to be set up to address this question.</p> <p>If GMP were adopted, no new licences would be required. If GMP were not adopted, a licence to manufacture products could be issued under the Misuse of Drugs Act 1975.</p>
Importing	<p>A licence to import controlled drugs - issued by Medicines Control.</p> <p>One of the following licences is also required:</p>	<p>A licence to import cannabis would be issued by the Agency. One or more of the following licences would also be required:</p>

Activity	Current Licensing or Assessment	Proposal for the Scheme
	A licence to deal in controlled drugs - issued by Medicines Control. A licence to grow prohibited plants - issued by Medicines Control.	A licence to deal in controlled drugs - issued by Medicines Control A licence to grow cannabis could be issued by the Agency A licence to manufacture products could be issued under the Misuse of Drugs Act 1975.
Exporting	A licence to export controlled drugs - issued by Medicines Control. One of the following licences is also required: A licence to deal in controlled drugs - issued by Medicines Control. A licence to grow prohibited plants - issued by Medicines Control.	A licence to export cannabis would be issued by the Agency. One of the following licences would also be required: A licence to deal in controlled drugs - issued by Medicines Control A licence to grow cannabis could be issued by the Agency A licence to manufacture products could be issued under the Misuse of Drugs Act 1975.
Assessing products	Consented products are assessed by Medsafe Unconsented products are currently not assessed – the prescriber determines their suitability on a case-by-case basis.	Need to investigate and analyse different quality standards which are used and whether or not they are appropriate for this scheme. A working group needs to be set up to address this question. Consented products would continue to be assessed by Medsafe Unconsented products could be assessed by: the prescriber (status quo) the Agency third party approved by the Agency
Distributing products	Licence to deal in controlled drugs – issued by Medicines Control Licence to wholesale medicines – issued by Medicines Control	This is not proposed to change.
Pharmacy licensing (patients access products via pharmacies)	Pharmacies are licensed by Medicines Control	This is not proposed to change. Could restrict products to some pharmacies only.
Access for patients via prescription	Medicines Control and the Chief Medical Officer assessing applications for the prescribing of cannabis products.	Prescribing requirements for cannabis products are being reviewed by the Medicinal

Activity	Current Licencing or Assessment	Proposal for the Scheme
		Cannabis Interim Advisory Committee.
Post-market surveillance, compliance, auditing and recalls	Post-market surveillance, compliance, auditing and recalls are monitored by Medsafe	Post-market surveillance, compliance and auditing is not proposed to change. Recalls could be managed by the Agency – this could depend on how it is determined that the product quality standard is met.
INCB reporting	Currently done by Medicines Control who receive the information from licensees as part of their requirements (specified in the Misuse of Drugs Regulations 1977).	This is not proposed to change. The Agency would work with Medicines Control to ensure information on cannabis products is reported to the INCB.

Appendix 2: Status of work streams, priorities and resourcing implications

Work Stream	Priority for completion	Status	Resources
Secretariat support for the Interim Advisory Committee meeting.	High	In progress	RPA (lead) Medicines Control Policy
Supporting the Health Committee's consideration of the Misuse of Drugs Amendment Bill	High	In progress	Policy (lead) Health Legal Medicines Control RPA
Quality standards that all medicinal cannabis products will be required to meet (products)	High	Yet to start	RPA (lead) Medicines Control Policy Medsafe (Product Regulation)
Growing standards that medicinal cannabis growers will be required to meet (growers)	High	Yet to start	RPA (lead) Medicines Control Policy
Manufacturing standards that medicinal cannabis processors and manufacturers will be required to meet (manufacturers)	High	Yet to start	RPA (lead) Medicines Control Policy
Legislative options for allowing a list of products which meet the quality standards to be released (advertising)	High	Yet to start	Health Legal (lead) Policy Medicines Control/RPA

Work Stream	Priority for completion	Status	Resources
Confirming proposed scheme meets international obligations	High	Yet to start	RPA (lead) Health Legal
Stakeholder engagement and consultation	High	In progress	Policy (lead) RPA Medicines Control
Providing guidance information to industry and the public (growers, manufacturers, prescribers, patients).	High	In progress and ongoing	Policy RPA Medicines Control Health Legal Comms
Interface of the scheme with other legislation (Medicines/Therapeutics, Smokefree environments, Hemp Regs).	Medium	Yet to start	RPA (lead) Medicines Control Policy Health Legal
Types of licences, licensing requirements and form of licences	Medium	Yet to start	RPA (lead) Medicines Control Health Legal Policy
Developing regulations to implement the licensing scheme and fees	Medium	Yet to start	Policy (lead) Health Legal (lead) RPA Medicines Control
Budgeting and resourcing for the Agency (confirming budget, identifying required skills and experience, training needs, recruitment)	Medium	Yet to start	RPA (lead)
Compliance Activities	Medium	Yet to start	RPA (lead)
Transitional arrangements for existing licences and products supplied under section 29	Low	Yet to start	Policy (lead) Health Legal RPA Medicines Control
Internal procedures for the Agency	Low	Yet to start	RPA (lead)

Appendix 3: Core project team

The core project team will have input as required across all of the work streams:

- Andrea Eng (RPA)
- Vidhiya Damodaran (RPA)
- Sue Scott (Medicines Control)
- Sharon Woollaston (Policy)
- Asti Laloli (Policy)
- Haley Ataera (Policy)
- Emma Hindson (Policy)
- Helen Fielding (Policy)
- Veronika Munro (Project manager)
- Jane Hubbard (Health Legal).

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