

# Medicinal Cannabis Scheme Consultation: Short Guide

Consultation on the regulations for a Medicinal Cannabis Scheme in New Zealand closes on Wednesday 7 August 2019 at 5 pm. Your feedback will help shape the final proposals. We appreciate you taking the time to make a submission.

This short guide provides an overview of the scope of the Scheme and highlights some key information for different groups: patients/consumers, industry, researchers, prescribers and pharmacists. As with any snapshot, it leaves a lot out. People will still need to read the relevant parts of the full consultation document before submitting.

## Overall objectives of the Scheme

- The Scheme aims to improve patient access to quality medicinal cannabis products. To achieve this, the Scheme needs to enable the cultivation of cannabis and the manufacture of medicinal cannabis products in New Zealand, and the ongoing importing of overseas products to encourage competition and improve affordability of quality products.
- A key component of the Scheme is to require that all products supplied under the Scheme meet minimum standards of quality.
- The Scheme needs to provide medical practitioners (doctors) and nurse practitioners with confidence about the range of quality medicinal cannabis products available to prescribe.
- The Scheme must recognise the principles of Te Tiriti o Waitangi (the Treaty of Waitangi) and support equitable health outcomes while supporting consumer access to, and individual responsibility for, their medical care.
- The design and implementation of the Scheme should also enable equity of access to the economic benefits of a medicinal cannabis industry, while supporting New Zealand's trade and economic objectives.

## What the Scheme does and does not cover

- The Scheme will set out minimum standards for the cultivation of cannabis and manufacture of medicinal cannabis products, and specifications for the finished products.
- All participants in the industry will need to apply for and hold current licences for the cultivation, manufacture and supply of medicinal cannabis.
- The Scheme will only cover medicinal cannabis products originating from the cannabis plant.
- Cultivating cannabis for recreational use is not part of the Scheme. New Zealanders will choose whether or not to legalise recreational cannabis as part of a referendum at the 2020 General Election.
- Medicinal cannabis products will only be available as prescription medicines, prescribed by a medical practitioner (doctor). When approved CBD (cannabidiol) products become available, these will also be able to be prescribed by a nurse practitioner.

## Responding to the consultation document

All the proposals and consultation questions can be found within the public consultation document and in Part H (pages 70–86). They are also in the online consultation tool ([health.govt.nz/publication/medicinal-cannabis-scheme-consultation](https://health.govt.nz/publication/medicinal-cannabis-scheme-consultation)), which is our preferred way to get feedback. All the questions in the public consultation document are colour coded.

There are specific questions for industry, researchers, prescribers, pharmacists, patients/consumers, and for everyone ('all'). We encourage you to answer or provide comments on any proposals or questions you feel are relevant to your area or areas of interest.

### **Key proposals, questions and information for different audiences**

The question at the heart of the consultation is whether the current proposals and options meet the Government's objective of improving patient access to quality medicinal cannabis products. Below we detail some of the key questions, proposals, options and information for different audiences.

### **Key proposals and information for all audiences**

- Proposed quality standards for medicinal cannabis products are a key part of the Scheme. The proposals cover standards for cultivating and manufacturing medicinal cannabis products, the active pharmaceutical ingredients (API), which produce the effects of the drugs, and the finished products – for example, pills, balms, nasal sprays. (See pages 10–30.)
- Medicinal cannabis products for smoking and edible products containing cannabis are not proposed to be allowed under the Scheme. Medicinal cannabis products for vaping are proposed to be allowed.
- Cannabis-based dietary supplements, natural health products or nutraceuticals would have to meet the requirements of the Scheme, with all products being prescription-only (pages 24–25).

### **Key proposals and information for industry**

- There are proposed fees and licensing charges for the cultivation, manufacturing, packaging and labelling, supplying, importing and exporting of medicinal cannabis products (pages 65–69).

- We are proposing not to allow the export of unprocessed or bulk raw cannabis (pages 31–41).
- Industrial hemp growers would be able to supply seeds to medicinal cannabis licensees (page 37).
- The proposed cut off between small and large scale cultivation is 200 square meters (page 35).
- Proposed controls after products go to market include: investigation of quality, complaints, product recalls and enforcement powers (pages 61–64).

### **Key proposals and options for prescribers and pharmacists**

- It is proposed that unapproved medicinal cannabis products will not be required to have clinical trial data, which is the same as for other unapproved medicines. We are asking how comfortable prescribers would be with prescribing products that have not undergone clinical trials (pages 58–59).
- It is proposed that there will no longer be a requirement to obtain Ministry of Health approval to prescribe products that meet the quality standards.
- It is proposed that approved medicinal cannabis products that are controlled drugs will be able to be prescribed by medical practitioners (doctors) without the need for a recommendation from a specialist for approved uses (known as 'on-label' use).

### **Key question for researchers**

- Will the proposed fees for licences affect the ability to research medicinal cannabis products? (pages 65–69).

### **Contact details**

If you have any questions, please contact [medicinal\\_cannabis@health.govt.nz](mailto:medicinal_cannabis@health.govt.nz)