Submission Form for the Public Consultation on the New Zealand Medicinal Cannabis Scheme

Instructions

Please refer to the consultation document to assist in your consideration of these questions.

Our online tool, CitizenSpace, is our preferred way to get feedback and can be accessed here: https://consult.health.govt.nz/medsafe/medicinal-cannabis-scheme-consultation/

If you are using this template instead, please email it to: medicinal_cannabis@health.govt.nz

Submitters are asked to provide the following information:

This submission was completed by:		
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Position/Profession (if applicable/relevant):		Public Health Advisor

Are you submitting this *(tick one box only in this section)*:

☐	as an individual or individuals (not on behalf of an organisation)
☒	on behalf of a group or organisation(s)

Please do not to include information that identifies people breaking the law. If you are an individual or individuals and you check the following box, the Ministry of Health will remove your personal details from your submission, and your name(s) will not be listed in the published summary of submissions.

☐	I do not give permission for my personal details to be released.

The above information will be taken into consideration if your submission is requested under the Official Information Act 1982. People in New Zealand can request information from government and government agencies under the OIA. This information will be made available unless there is a good reason to withhold it. The OIA is important for ensuring government is open and transparent.

If you are an individual or individuals, please indicate which group you identify with / your submission represents (you may tick more than one box in this section):

☐	Consumer/Patient	☐	Māori
☐	Medical practitioner (doctor)	☐	Pacific
☐	Nurse practitioner	☐	Asian
☐	Pharmacist	☐	Pākehā/European
☐	Medical – other		
☐	Researcher/Academic	☐	Other – *(please specify)*:
☐	Industry *(please specify)*:		

If you are an organisation, please indicate which group you identify with / your submission represents (you may tick more than one box in this section):

☐	Consumer/patient group	☐	Local government
☐	Medical professional association	☐	Industry: hemp
☐	Pharmacy professional association	☐	Industry: medicinal cannabis cultivate
☐	Nurse professional association	☐	Industry: medicinal cannabis manufacture
☐	Other professional association	☐	Industry: medicinal cannabis supply
☐	Non-governmental organisation	☐	Industry: Māori
☐	Academia/Research institute	☐	Māori: other group
☐	District health board		
☐	Central government	☒	Other *(please specify)*: Public Health Unit

Medicinal Cannabis Scheme Consultation Proposals and Questions

In this table, we note the audience(s) we think the proposal and/or question is most relevant for. For example, much of Part E: Prescribing has questions for prescribers, though some of these may also be of interest to consumers, industry or other groups. We encourage you to answer or provide comments on any proposals or questions you feel are relevant. Questions are coloured by audience: **all**, **industry**, **patients/consumers**, **pharmacists**, **prescribers**, **researchers.**

Overall consultation document

Questions for all:

1. Please provide here any overall comments on the proposals in the consultation document.

Comments:

Regional Public Health recognises the goals of the medicinal cannabis scheme to deliver quality, affordable products to patients and be commercially sustainable, but there are some elements which need further consideration.

a. **Smoke free Medicinal Cannabis**

Medicinal cannabis must be smoke-free. New Zealand has a goal of being smoke free by 2025. It is very important that if patients are prescribed dried cannabis, that they also be able to acquire affordable medical vaping equipment. Otherwise, cannabis products which are not smoked, such as tablets, tinctures and balms, should be prescribed for patients who are unable to afford vaping equipment.

New Zealand has unequal cancer treatment outcomes for indigenous, marginalised and socioeconomically disadvantaged populations. Cancer drives a large and increasing proportion of avoidable mortality for Māori and Pasifika (Teng et al, 2016). If dried cannabis leaf is prescribed to patients without support for buying vaping equipment, there is an increased likelihood that lower income and marginalised communities will smoke cannabis and as a result, experience disproportionate harms. Another common issue is the co-use of cannabis leaf with tobacco. Co-use of tobacco with cannabis increases the likelihood of a person becoming cannabis dependent (Rabin & George, 2015) and exposes the patient to greater respiratory harm. It is vital that this is discouraged.

b. **Public perception of medicinal cannabis**

Clear messaging and education of the public on cannabis is crucial. Some communities hold misconceptions about cannabis. Some common misconceptions are that cannabis is less harmful than other medications because it is a 'natural' plant, and overall, an overstated therapeutic potential for cannabis (The Lancet Neurology, 2018). These ideas could lead to harmful use. Our communities need an understanding of what conditions medicinal cannabis might be helpful for, but also the limitations of the drug.

Overall, there is a paucity of evidence on the effectiveness of medicinal cannabis. Strong anecdotal evidence has led many people to believe that the therapeutic effects of

cannabis are potentially greater than they actually are (Glass & Ashton, 2019). The overstated potential of cannabis might lead some communities to seek illegal cannabis when unable to get a prescription from a doctor. Cannabis on the black market is known to have low levels of CBD and higher levels of THC, which may increase the potential for harm.

Cannabinoids have been considered for the treatment of psychiatric conditions (Newton-Howes, 2017). However, there needs to be greater public understanding of cannabinoid use for these purposes, as there is potential for harm in an already vulnerable patient group. There is also evidence of an association between cannabis use, psychosis, and poor psychological outcomes, especially for younger people (Newton-Howes, 2017). As such, it is important to use health promotion and education to improve community understanding of the complexities of cannabis, in order to avoid it being perceived as a 'cure-all'.

c. **Advertising**
Medicinal cannabis should not be advertised. Recently, there have been billboards in Auckland with the message "cannabis is medicine" (Glass & Ashton, 2019). In New Zealand, medication advertisements must usually contain mandatory information about the medication, which this advertisement did not (Medsafe, 2011). Overall, advertising of medicinal cannabis may increase harm by creating public misconceptions about the drug. Doctors should be upskilled to provide accurate information about medicinal cannabis.

d. **THC and other cannabinoid content and dosage**
Further and thorough research into THC use for medicinal purposes should be prioritised, as there are known negative side-effects. Cannabis contains hundreds of cannabinoids, almost all of which we have limited knowledge of. This makes it difficult to ascertain the harm profile of each cannabinoid. The harms of illegal cannabis use are often attributed to the high THC content. THC is associated with dependence, cognitive and educational impairment and psychosis (Englund, Freeman, Murray, & McGuire, 2017). Further research is required to establish which types of cannabis should be prescribed for which conditions, and what dose should be given (McCall, 2015).

e. Medicinal cannabis treated as a medicine
RPH supports New Zealand Medical Association's position that medicinal cannabis should be treated like other medicines. Internationally, there has been a shift away from the prohibition of cannabis, for both medicinal and recreational use. It is very important for the two separate issues of medical and recreational use not be conflated (Newton-Howes, 2017). Doctors should only prescribe medicinal cannabis for well-defined medical reasons, and the risks of cannabis should be considered in a similar way to those of other existing medications (NZMA, 2017).

2. Do you think the current proposals and options in this document would meet the Government's objective of improving patient access to quality, affordable medicinal cannabis products?

Yes ☐	No ☐	Don't know ☐	

Please explain why/why not:

A4 - Equity

There should be equity of access to the economic benefits of a medicinal cannabis industry. It is important that the Medicinal Cannabis Agency has the capacity and capability to support iwi and other Māori groups to understand the medicinal cannabis requirements for industry.

Question for all:

3. What do you think is the best way to achieve equity of access to the economic benefits of a medicinal cannabis industry?

Comments:

Question for all:

4. Have you (or someone you know) had difficulty in accessing medicinal cannabis products (eg, due to cost, availability of products, patient–prescriber relationship, information on products available)?

Yes ☐	No ☐	Don't know ☐	

If yes, please provide comments as to why:

Questions for prescribers:

5. As a prescriber, what do you see as the barriers to patient access to medicinal cannabis products?

Comments:

Please indicate your position on the following statement:

6. 'There are greater barriers to accessing medicinal cannabis products for particular patients.'

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

If you agree, please discuss the barriers:

B2 - Proposed quality standards for cultivation:

There are three proposed options for a quality standard for cultivation:

A. Manufacturer sets a process or a starting material product standard.

B. Regulator sets a cultivation process standard.

C. Regulator sets quality standard for starting material.

Questions for industry or researchers:

7. Do you or your organisation currently hold a licence to cultivate cannabis for medicinal or scientific research purposes?

Yes ☐	No ☐	

8. How likely are you to apply for a licence to commercially cultivate cannabis for medicinal purposes?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

Comments:

9. Which option for cultivation standards do you prefer?

A. Manufacturer sets a process or a starting material product standard.
B. Regulator sets a cultivation process standard.
C. Regulator sets quality standard for starting material.

A ☐	B ☐	C ☐	Don't know ☐	Other ☐	

Comments:

10. In your view, what are the advantages and disadvantages of each of the options?

Comments:

11. If you prefer option B (Regulator sets a cultivation process standard), which of the following cultivation process standards would be your preference?

WHO GACP ☐	NZ GAP ☐	EU GACP ☐	None ☐	Don't know ☐	Other ☐

Comments:

12. How likely are you to apply for a licence to commercially cultivate cannabis for medicinal purposes if option A (Manufacturer sets a process or a starting material product standard) was the preferred option?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐
Comments:					

13. How likely are you to apply for a licence to commercially cultivate cannabis for medicinal purposes if option B (Regulator sets a cultivation process standard) was the preferred option?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐
Comments:					

14. How likely are you to apply for a licence to commercially cultivate cannabis for medicinal purposes if option C (Regulator sets quality standard for starting material) was the preferred option?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☒
Comments:					

15. How many cultivation sites are you planning?

None ☐	One ☐	Two ☐	Three ☐	Four or more ☐	Don't know ☐
Comments:					

16. What would be the average size of each cultivation area?

Less than $100m^2$ ☐	100 - $200m^2$ ☐	200 - $500m^2$ ☐	500 - $1000m^2$ ☐	More than $1000m^2$ ☐	Don't know ☐
Comments:					

17. Do you have any additional comments on the proposed options for cultivation standards?

Comments:

B3 - Proposed quality standards for manufacturing

There are two options for a manufacturing process quality standard.

A. Adopt the current New Zealand approach for manufacturing in accordance with Good Manufacturing Practice (GMP) (Medicines Act) for all medicinal cannabis products.

B. Allow for the manufacture of some medicinal cannabis product dose forms under GMP (Medicines Act) and some medicinal cannabis dose forms under Good Production Practices (GPP) (Misuse of Drugs Act).

Questions for all:

18. What is your preferred manufacturing standard for medicinal cannabis products in New Zealand?

A (GMP) ☒	B (GMP and GPP) ☐	Don't know ☐	Other ☐

Comments: Good Manufacturing Practice (GMP) is the higher pharmaceutical standard, which is preferable to RPH.

19. If you prefer allowing GPP for some prescription medicines, which dose forms of medicinal cannabis products should be allowed to be manufactured to GPP?

Dried cannabis ☐	Cannabis oils ☐	Ointments, creams, or topical balms ☐	Tablets, capsules, or other oral dose forms ☐	Transdermal patches ☐
None ☐	Not applicable ☐	Don't know ☐	Other ☐	

Please indicate your position on the following statements:

20. 'New Zealand should only allow GMP as the manufacturing standard for medicinal cannabis products'

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☒	Strongly agree ☐	Don't know ☐

Comments:

21. 'New Zealand should allow GPP as the manufacturing standard for some forms of medicinal cannabis products (eg, dried cannabis and cannabis oils).'

Strongly disagree ☐	Disagree ☒	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐
Comments:					

22. Do you think medicinal cannabis products should be manufactured to the same standard with regard to consistency and quality as other medicines?

Yes ☒	No ☐	Don't know ☐	
Comments:			

23. Do you have any additional comments on the proposed options for manufacturing medicinal cannabis products?

Comments:

24. We are seeking information that compares the cost to the public of the same product under GPP and under GMP. Do you have any information you can share on potential or actual product costs under either option?

Yes ☐	No ☒	
Comments:		

Questions for industry:

25. Do you currently hold a Licence to Manufacture Medicines?

Yes ☐	No ☐	

26. How likely are you to apply for a Licence to Manufacture Medicinal Cannabis Products?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐
Comments:					

27. How likely are you to apply for a Licence to Manufacture Medicinal Cannabis Products if the preferred manufacturing standard for all medicinal cannabis products is GMP?					
Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐
Comments:					

28. How likely are you to apply for a Licence to Manufacture Medicinal Cannabis Products under GPP if it is an option for some dose forms (for example, dried cannabis, and cannabis oils)?					
Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐
Comments:					

29. What types of medicinal cannabis products do you intend to manufacture?				
Dried cannabis ☐	Cannabis oils ☐	Ointments, creams, or topical balms ☐	Tablets, capsules, or other oral dose forms ☐	Transdermal patches ☐
Other ☐	Don't know ☐			
Comments:				

30. If you are intending to manufacture medicinal cannabis products to GMP, in what timeframe (from the start of the Medicinal Cannabis Scheme) do you think you will have products available for assessment for supply?			
0-3 months ☐	3-6 months ☐	6 months – 1 year ☐	1 – 2 years ☐
More than 2 years ☐	Not applicable ☐	Don't know ☐	

31. If you are intending to manufacture medicinal cannabis products to GPP, in what timeframe (from the start of the Medicinal Cannabis Scheme) do you think you will have products available for assessment for supply?

0-3 months ☐	3-6 months ☐	6 months – 1 year ☐	1 – 2 years ☐
More than 2 years ☐	Not applicable ☐	Don't know ☐	

32. We are seeking information that compares the cost to the public of the same product under GPP and under GMP. Do you have any information you can share on potential or actual product costs under either option?

Yes ☐	No ☐	

If yes, please provide details:

Questions for prescribers:

33. How likely are you to prescribe a medicinal cannabis product that has been manufactured to GMP?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

Comments:

34. How likely are you to prescribe a medicinal cannabis product that has been manufactured to GPP?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

Comments:

B4 - Proposed quality standards for active pharmaceutical ingredients

The proposed quality standard for active pharmaceutical ingredients (APIs) is the product specifications set out in the New Zealand Product Quality Standards Monograph (see Appendix 2).

Question for industry:

35. If you are manufacturing API, how likely are you to apply for a licence to manufacture them if API are required to meet quality standards?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐
Comments:					

Questions for all:
What is your opinion of the following proposal:

36. All active pharmaceutical ingredients (API) should be required to meet the requirements of the New Zealand Product Quality Standards Monograph (see Appendix 2).

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐
Comments:					

37. Do you have any additional comments on the proposed option for the API product quality standard?

Comments:

B4 - Finished product quality standard – dose form requirements

Medicinal cannabis products that are intended to be smoked, and food containing medicinal cannabis, will not be allowed under the Medicinal Cannabis Scheme.

It is proposed that the following dose forms would only be allowed if they are approved or provisionally approved under the Medicines Act:

- modified-release dose forms
- sterile dose forms (injectables, and eye and ear preparations).

Questions for all:
Please indicate your position on the following statement:

38. 'It is proposed that the finished product quality standard should include the dose form requirements.'

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☒	Don't know ☐
Comments:					

39. Should there be a limit on the amount of active pharmaceutical ingredient in each dose?

Yes ☒	No ☐	Don't know ☐	

If yes, what do you think the limit per dose should be? See answer to Q. 40 below.

40. Do you have any additional comments on the proposed dose form requirements?

Comments: Dose should be informed by clinical trials of the cannabinoids. Many of the side effects of cannabis are dose dependent, and further research is required.

Questions for prescribers:

41. What types of products would you be most likely to prescribe?

Dried cannabis ☐	Cannabis oils ☐	Ointments, creams, or topical balms ☐	Tablets, capsules, or other oral dose forms ☐	Transdermal patches ☐
Other ☐	Don't know ☐			

42. If you were to prescribe medicinal cannabis products, which route of delivering the medicine would you be most likely to prescribe?

Oral ☐	Inhalation ☐	Patch (transdermal) ☐	Creams or ointments (transdermal) ☐	Under the tongue (sublingual) ☐
Other ☐	Don't know ☐			

Comments:

B4 - Finished product quality standard – product specifications

The proposed finished product quality standard includes the product specifications set out in the New Zealand Product Quality Standards Monograph (see Appendix 2), plus dose form requirements, stability and shelf life requirements, packaging and labelling requirements, and quality requirements for excipients.

Questions for industry:

43. How likely are you to apply for a licence to manufacture based on the requirements of the proposed quality standard for finished products?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

Comments:

44. What is your opinion of the proposal that the finished product quality standard should include the above requirements?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Comments:

B4 - Testing to meet the product quality standards

It is proposed that each batch of API and finished product will be required to be tested and that evidence is provided to the regulator to verify that the product meets the quality standards.

The evidence required would be Certificates of Analysis, which certifies that the product meets the required product specifications and gives additional evidence supporting compliance with stability, shelf life, packaging and labelling, excipient and dose form requirements.

Questions for industry:
Please indicate your position on the following proposal:
45. 'Batch testing should be required to provide evidence that the product meets the requirements of the product quality standard.'

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Comments:

46. Do you have any additional comments on the proposed testing requirements?

Comments:

C3 - Licensing under the Scheme

It is proposed that the general licensing requirements listed in Section C3 must be met for all licence applications.

Questions for industry:
47. Are any of the proposed licensing requirements likely to impact on your ability to apply for a licence?

Yes ☐	No ☐	Don't know ☐	
If yes, please provide details:			

48. Do the proposed licensing requirements create equity issues about who is able to enter the sector? For example, are there any barriers to obtaining a licence to cultivate for growing on Māori land?

Yes ☐	No ☐	Don't know ☐	
Comments:			

C4 - Licence to Cultivate

It is proposed that the licensing requirements listed in part C4 must be met in additional to the general licensing requirements in part C3.

Question for industry and researchers:

49. Are any of the proposed licensing requirements likely to impact on your ability to apply for a licence to cultivate?

Yes ☐	No ☐	Don't know ☐	
If yes, please provide details:			

50. What are your views on the proposal to allow growers of industrial hemp to be able to supply seeds to medicinal cannabis licensees and industrial hemp licensees?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐
Please explain:					

51. What are your views on the proposal to allow medicinal cannabis licensees to be able to supply seeds to industrial hemp licensees?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐
Please explain:					

It is proposed that there are two types of licences – one for 'small scale' (cultivation area less than 200 m^2) and one for 'large scale' (cultivation area greater than 200 m^2).

Question for industry and researchers:

52. Is the proposed 200 m^2 cultivation area an appropriate cut-off level between small-scale and large-scale cultivation?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Please provide comment:

C5 - Declaration to allow the use of local varieties

We are proposing that a licence holder will be able to use local varieties of cannabis for cultivation. To do this, the licence holder will need to make a declaration to allow them to use the seeds to be legally grown in New Zealand.

Question for all:

53. Should there be limits on the amount of seed or the number of declarations that could be allowed?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☒	Don't know ☐

Please provide an explanation for your view:
It would be preferable to limit the size of the medicinal cannabis industry in New Zealand.

C6 - Transition from research to commercial

We propose to allow a small number of plants to be transferred from a licence to cultivate cannabis for scientific and medical research to a licence to cultivate cannabis for commercial purposes.

Question for industry and researchers:

54. What would be the minimum number of plants you require to retain in order to maintain specific cultivars, when moving from a research to a commercial cultivation operation?

Less than 20 ☐	20-40 ☐	40-60 ☐	60-80 ☐	More than 80 ☐	Don't know ☐

Please provide justification for numbers suggested:

C7 - Licence to Manufacture

It is proposed that the **licensing requirements** listed in Section C7 must be met in addition to the general licensing requirements in Section C3.

Question for industry:

55. Are any of the proposed licensing requirements likely to impact on your ability to apply for a licence to manufacture?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

If yes, please provide details:

C8 - Licence to Sell Medicines by Wholesale

A Licence to Sell Medicines by Wholesale issued under the Medicines Act is required for distribution of CBD products by wholesale. It is proposed that any CBD products supplied must, as a minimum, meet the finished product quality standard, which includes the New Zealand Product Quality Standards Monograph (see Appendix 2) and requirements for dose form, packaging and labelling, stability and shelf life, and excipients. Evidence must be provided to the regulator that verifies that the products meet the finished product quality standard.

Question for industry:

56. How likely is this proposed requirement to impact on your ability to apply for a licence to sell medicines (CBD products) by wholesale?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

Please explain:

C9 - Licence to Supply Unconsented Medicinal Cannabis Products under Misuse of Drugs Act

It is proposed that products, as a minimum, must meet the finished product quality standard, which includes the New Zealand Product Quality Standards Monograph (see Appendix 2) and requirements for dose form, packaging and labelling, stability and shelf life, and excipients. Evidence must be provided to the regulator that verifies that the products meet the finished product quality standard before they can be supplied.

It is further proposed that these requirements would apply to both imported and locally manufactured products.

Questions for industry:

57. How likely are these requirements to impact on your ability to apply for a Licence to Supply Unconsented Medicinal Cannabis Products under the Misuse of Drugs Act?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

If yes, please explain why:

58. Do you have any additional comments on the proposed options for supplying medicinal cannabis products?

Comments:

C12 - Import

All imported or exported products must, as a minimum, meet the New Zealand product quality standards.

Questions for industry:

59. Based on the proposals outlined in Section C12, how likely are you to import medicinal cannabis products?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

Comments:

60. How likely are these requirements to impact on your ability to apply for a Licence to Supply Unconsented Medicinal Cannabis Products under the Misuse of Drugs Act?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

Please explain:

Question for all:

61. What forms of medicinal cannabis products are you interested in importing?

Dried cannabis ☐	Cannabis oils ☐	Ointments, creams, or topical balms ☐	Tablets, capsules, or oral dose forms ☐	Transdermal patches ☐
Other ☐	Don't know ☐			

Comments:

C12 - Export

(a) In order to continue to meet our international obligations under the Single Convention on Narcotic Drugs 1961 and to minimise the risk of diversion, we are proposing to **not** allow for the export of unprocessed or bulk raw cannabis. This restriction does not apply to final dose form, standardised, packaged and labelled raw cannabis that meets the New Zealand product quality standards and that can be exported into medicinal markets overseas under the conditions of an export licence.

(b) All imported or exported products must, as a minimum, meet the New Zealand product quality standards.

Question for industry:

62. How likely are you to export medicinal cannabis products based on the above proposals?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

Comments:

63. If allowed, what type of medicinal cannabis product would you be interested in exporting?

Starting material ☐	API ☐	Bulk finished product ☐	Finished products ☐	Other ☐	Don't know ☐

Comments:

64. What finished dose forms of medicinal cannabis products are you interested in exporting?

Dried cannabis ☐	Cannabis oils ☐	Ointments, creams, or topical balms ☐	Tablets, capsules, or oral dose forms ☐	Transdermal patches ☐
Other ☐	Don't know ☐			

Comments:

Question for all:

65. Should the export of unprocessed or bulk raw cannabis be allowed?

Yes ☐	No ☐	Don't know ☐	
Please explain why/why not:			

D - Distribution

We propose that if the Medicinal Cannabis Agency was satisfied that a product meets the Scheme's quality standards, it would allow the supply of that product via a licence.

Question for industry:

66. Do you have any comment on the proposal that a product can only be supplied under licence if it meets the requirements of the product quality standards?

Comments:

E1 - Approval to prescribe

The proposal is that Ministry of Health approval to prescribe is not required for any medicinal cannabis products that meet the minimum quality standards.

Question for prescribers:

67. Would you support another means of oversight in a prescribing decision, eg, peer review (a colleague to peer review a prescribing decision)?

Yes ☐	No ☐	Don't know ☐	
Do you have any suggestions for the oversight required?			

Question for prescribers and pharmacists:

68. Do you understand the current requirements for prescribing medicinal cannabis products?

Yes ☐	No ☐	Don't know ☐	
Comments:			

Question for all:

69. Do you have any additional feedback on the proposals for prescribing medicinal cannabis products?

Comments:

E1 - On-label use of approved products

This proposal is for the **uses** of the product approved by the Ministry of Health (known as "on-label" uses). It is proposed that approved medicinal cannabis products that are controlled drugs can be prescribed by medical practitioners (doctors) without the need for a recommendation from a specialist for "on-label" (approved) uses.

Questions for prescribers:

70. What is your opinion on the proposal to remove the current requirement for a specialist recommendation for medical practitioners (doctors) to prescribe?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Comments:

71. If you agree that the requirement for a specialist recommendation should be removed, should prescribing of medicinal cannabis products remain under the care of specialists in some circumstances (eg, prescribing medicinal cannabis products to children)?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐
Not applicable ☐					

Comments:

72. Do you currently prescribe medicinal cannabis products that are controlled drugs for on-label use?

Yes ☐	No ☐	

Please explain why or why not:

If yes, then how often?

73. If the requirement for a specialist recommendation were removed, would you prescribe medicinal cannabis products that are controlled drugs for on-label use?

Yes ☐	No ☐	Don't know ☐	

Please explain why or why not:

E1 - Off-label use of approved products

This proposal is for the unapproved **uses** of a medicinal cannabis product (known as "off-label" uses). It is proposed that **approved** medicinal cannabis products that are controlled drugs can be prescribed by a specialist, or by a medical practitioner (doctor) with a specialist recommendation for these "off-label" uses, without the need for Ministry approval to prescribe.

Questions for all:

74. It is proposed that off-label use of approved medicinal cannabis products that are controlled drugs (eg, Sativex) can be prescribed by a medical practitioner with a specialist recommendation. Do you agree with this proposal?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Please explain why or why not:

75. It is proposed that Ministry of Health approval to prescribe will not be required to prescribe approved medicinal cannabis products that are controlled drugs (eg, Sativex) for off-label use. Do you agree with this proposal?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Please explain why or why not:

Questions for prescribers:

76. Do you currently prescribe approved medicinal cannabis products (eg, Sativex) that are controlled drugs for off-label use?

Yes ☐	No ☐	

If yes, then how often?

77. If the requirement for Ministry of Health approval to prescribe were removed, would you prescribe approved medicinal cannabis products (eg, Sativex) that are controlled drugs for off-label use?

Yes ☐	No ☐	Don't know ☐	

Please explain why or why not:

E1 – Unapproved, controlled drugs that meet the quality standards

It is proposed that Ministry of Health approval to prescribe will not be required for unapproved medicinal cannabis products that are controlled drugs that meet the quality standards.

Question for all:

78. Do you agree with this proposal?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Please explain why or why not:

Questions for prescribers:

79. Do you currently prescribe unapproved medicinal cannabis products that are controlled drugs that meet any standards of quality?

Yes ☐	No ☐		

If yes, then how often?

80. If the requirement for Ministry of Health approval to prescribe were removed, how likely are you to prescribe medicinal cannabis products that are controlled drugs meeting the proposed product quality standard?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

Please explain why:

E1 - Unapproved, controlled drugs that do not meet the quality standards

No change is proposed for unapproved medicinal cannabis products that are controlled drugs that do not meet the quality standards. We propose these products can only be prescribed by a specialist and that Ministry of Health approval to prescribe is still required.

Question for all:

81. Do you agree with this proposal?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☒	Strongly agree ☐	Don't know ☐

Please explain why or why not:

Questions for prescribers:

Do you currently prescribe unapproved medicinal cannabis products that do not meet any standards of quality?

Yes ☐	No ☐		
If yes, then how often?			

82. Should Ministry of Health approval to prescribe unapproved medicinal cannabis products that do not meet the product quality standards continue to be required?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐
Comments:					

E1 - CBD products

No change is proposed for CBD products. These will still require a prescription from a medical practitioner if they are unapproved. A nurse practitioner can also prescribe them if they are approved or provisionally approved.

Questions for prescribers:

83. Do you currently prescribe CBD products?

Yes ☐	No ☐	
If yes, then how often?		

84. No change is proposed to the prescribing arrangements for CBD products. Do you agree with this proposal?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐
Comments:					

Question for all:

85. What are your views on the proposal not to change the prescribing arrangements for CBD products?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Please explain:

E3 - Provision of information to prescribers on prescribing of medicinal cannabis products.

The Medicinal Cannabis Scheme is proposing to not require clinical trials to be carried out for unapproved medicinal cannabis products (approved or provisionally approved medicinal cannabis products would require clinical trial data).

Question for all:

86. Would you expect an unapproved medicinal cannabis product to have undergone the same clinical trials as for an approved medicine?

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Please explain why or why not:

Questions for prescribers and pharmacists:

Please indicate your position on the following statements:

87. 'I would be willing to prescribe or dispense unapproved medicinal cannabis products that are controlled drugs that have not undergone clinical trials.'

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Comments:

88. 'I would be willing to prescribe or dispense unapproved CBD-products that are controlled drugs that have not undergone clinical trials.'

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Comments:

89. 'I would be comfortable prescribing or dispensing unapproved medicinal cannabis products that are controlled drugs that have not undergone clinical trials.'

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐
Comments:					

Questions for prescribers:

90. Do you have access to the information you need to prescribe medicinal cannabis products with confidence?

Yes ☐	No ☐	
Comments:		

91. If so, is it easy to understand?

Yes ☐	No ☐	
Comments:		

Questions for patients / consumers:

What is your position on the following statement:

92. "I would be comfortable taking medicinal cannabis products that have not been tested for safety and effectiveness".

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐
Please comment on whether this is true for certain types of products and not others:					

93. Should specialist approval be required when being prescribed medicinal cannabis products?

Yes ☐	No ☐	Don't know ☐	
Comments:			

94. Have you (or someone you know) been able to gain access to a specialist when required?

Yes ☐	No ☐	Don't know ☐	
Comments:			

F - Post Market Controls

As the medicinal cannabis products are medicines, some provisions of the Medicines Act will apply.

Question for all:

Please indicate your position on the following proposal:

95. 'The current post market monitoring and compliance requirements for medicines should be applied to all medicinal cannabis products.'

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☒	Don't know ☐
Comments:					

96. Do you have any additional comments on the proposed approach to post market monitoring and compliance?

Comments:

F - Enforcement Powers

We propose that the Medicinal Cannabis Agency will have the ability to:

- vary, suspend or revoke licences
- impose penalties for non-compliance with the quality standards, product information requirements or licence conditions
- order the seizure and destruction of products manufactured or distributed without the relevant licence.

Question for all:

97. Do you have any comments on the proposed enforcement powers?

Comments:

F - Collection of Information

The Medicinal Cannabis Agency will survey health practitioners about their confidence and willingness to prescribe products, the conditions that the products are being used to treat, and their effectiveness in use.

Question for all:

98. In your opinion, what is the key information the agency needs to collect to monitor progress against the objectives of the Scheme?

Comments:

G - Fees

It is proposed that the fees set under the Medicinal Cannabis Scheme enable full cost recovery of the cost of issuing licences to:

a) Cultivate Medicinal Cannabis
b) Manufacture Medicinal Cannabis Products
c) Pack Medicinal Cannabis Products
d) Supply an Unconsented Medicinal Cannabis Product.

Existing licence fees under the Medicines Act and the Misuse of Drugs Act will continue to apply for existing licences.

Question for researchers:

99. Will the proposed fees affect your ability to research medicinal cannabis products or cannabis?

Yes ☐	No ☐	Don't know ☐	

Comments:

Questions for industry:

100. Based on the proposed fees, how likely are you to enter the medicinal cannabis market?

Very unlikely ☐	Unlikely ☐	Neither likely nor unlikely ☐	Likely ☐	Very likely ☐	Don't know ☐

Comments:

101. Which licence(s) do you intend to apply for within the next two years?

Licence to Cultivate ☐	Licence to Manufacture ☐	Licence to Supply ☐	Licence to Import ☐	Licence to Export ☐
Other ☐	Don't know ☐			

Question for all:

What is your position on the following statement:

102. 'The fee structure and approach are fair for both licence holders and the public.'

Strongly disagree ☐	Disagree ☐	Neither agree nor disagree ☐	Agree ☐	Strongly agree ☐	Don't know ☐

Comments:

103. Do you have any additional comments on the proposed approach to fees?

Comments:

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