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:		
	(name)	Richard Barge
Address:	*(street/box number)*	22 Gracechurch Drive
	(town/city)	Flat Bush, Auckland, 2016
Email:		exec@nzhia.com
Organisation (if applicable):		NZ Hemp Industries Association Inc
Position/Profession (if applicable/relevant):		Chairman

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)*:

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: The NZHIA supports any initiatives that create markets for industrial hemp, grown under licence and the production of hemp products which comply with other legislation in this case the Medicines Act, for local and export markets We support in principal the objectives of the scheme to improve patient access to quality, affordable medicinal cannabis products, providing prescribers with confidence about the quality of the medicinal cannabis products, supporting equitable health outcomes and access to the economic benefits of a medicinal cannabis industry, while supporting NZ trade and economic objectives. We have the opportunity to show the world how to use cannabis properly, foremost as a food and health product. We can choose to permit access to the wide range of products from hemp, which provide very little risk and realise the significant health benefits from good nutrition and a boost to our immune systems, reducing the future stress on for medical system by having a healthy pollution We have had world class industrial hemp regulations since 2006 (albeit not very well enabled currently), and we recommend you follow this "keep it simple" approach to the development of the Medicinal Cannabis Scheme. Your aim is to have a frame work that meets the above objectives, keeping compliance costs at an acceptable level, while producing appropriate quality product, ensuring medicinal cannabis is not diverted and that you meet your international reporting obligations. All these outcomes and objectives are in alignment with Industry. The standards and controls for producing and marketing medicinal products exist and do need to be duplicated in these regulations. The Medicinal Cannabis Scheme needs to provide a simple framework which will: 1) Allow the Medicinal Cannabis Agency to have access to the information to meet our international reporting obligations, mainly under the UN Single Convention

2) Issue licences to allow industry to achieve the objectives mentioned above, so we can realise the economic and trade benefits of providing quality, affordable products, prescribed with confidence. Products that meet the demands of a willing local and international consumer lead market.
3) Control THC while ensuring local industry is compliant with legislation and enabled to produce medicinal cannabis products
4) Establish a suitable pathway for consented and unapproved medical cannabis products to be marketed locally and exported, which allows NZ industry to scale and compete with imported product

This will require

1) Access to industrial hemp biomass and plants grown under an Industrial hemp licence. No duplication of licence is required. Low THC iHemp growers would be put off if they required a MODA cultivation licence costing $16-$23,000
2) Access to CBD must not be restricted to a prescription only and should be available as a non-medical product. Full spectrum and extracted dietary supplements, nutraceuticals and natural health products should be outside the scope of the medicinal cannabis scheme, as their quality requirements are covered by other legislation and compliance frameworks
3) Synthetic cannabinoids, are not naturally occurring and overseas experience shows the main adverse health effects are related to their use, this is an unnecessary increase in risk to medicinal cannabis use and they should therefore be banned
4) Support for medical professionals and industry to provide suitable information to give prescribers confidence in the content and use of medicinal cannabis products. These medical professionals have experience in prescribing other controlled drugs, which are not as safe as cannabis (opioids), so know how to evaluate the risks for their patients.
5) Amending the industrial hemp regulations to allow up to 1% THC, will create greater access to medicinal cannabis varieties, that will improve patient access and affordability and improve the economic outcomes for NZ
6) Introducing GMP requirements at the right level. Cultivators of starter material, primary processors and extractors provide API and plant matter that meets a manufactures specification. The GMP standard should start at this point, as the ingredients meet the spec, and the GMP compliant manufacturer produces the finished goods. Introducing GMP to the primary processors/cultivators will stop them entering the industry.
7) Cultivation standards should be set by the manufacture who is responsible for the quality of the finished goods

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:

This can be a yes, if the final framework incorporates the proposals and options that favour industry getting on with the job; of making products that consumers want and that medical practitioners and nurse practitioners can use and understand, yes it is possible to provide access to quality, affordable medicinal cannabis products.

Even with world class iHemp regulations, since 2006 the hemp industry is still not enabled, MOH interpretations continue to frustrate iHemp from being made into hemp products, which meet customer demand, pose no risk and comply with legislation. The Medicinal Cannabis Agency will need to commit to enabling the industry

MOH have the opportunity to achieve their objectives, but they will need to focus on keeping the approach simple. They will need to accept that industry wants the same outcomes and align the framework to the key industry objective, of facilitating the trade and economic outcomes.

If the scheme allows for this, it will be equitable in that Maori and NZ companies will have a level playing field to scale and produce high quality products at affordable prices, whilst keeping the doctors and patients informed.

Industry will be making major investments in capital and compliance. They will have to meet the requirements of the medicines act and other legislation when processing starter material into finished goods. Testing protocols will be important to ensure the required specification is meet throughout the value chain, which will also satisfy the regulators compliance requirements.

No licencees who has committed to this sort of investment wants to see any of their hemp diverted away from their markets. Industry will have tight controls on high THC products due to the higher risk of diversion and quality producers will always exceed best practices

The outcomes outlined in the consultation document, will accrue once we have the framework in place to allow the medicinal and non-medicinal industry to progress. How well this goes will be heavily dependant on these regulations enabling industry to progress

This starts with allowing exports to international markets whilst the NZ regulatory framework evolves to allow access to the same products available internationally.

To be equitable the licence costs will need to be reasonable and justified and must include the industrial hemp licence for the cultivation of low THC hemp

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: Keep the scheme simply and effective, allowing low THC industrial hemp to be grown under a hemp licence and higher THC material under a MODA licence, encouraging best practices, allowing contract manufactures to help new product development and start-up business to scale quickly to meet the demand for export products, both in the medical and non-medical markets.

The larger economic benefits from a medicinal cannabis industry are derived from the global market place for quality branded hemp products, made to high standards. This global market place does not always require products to be prescription medicines and this is why the supplement/nutraceutical market is a target for NZ producers.

Paragraph 107 brings in the non-medical uses of dietary supplements, natural health products and nutraceuticals into this scheme, we disagree with this as these areas are already covered by the industrial hemp regulations and existing legal frameworks, but for the terms of this consultation we will include comment on these non-medical uses.

By allowing the export of medical and non-medical products to international markets where they are legal we will develop economies of scale faster and this will provide lower cost products to local patients and will give New Zealanders access to the economic benefits of the medicinal cannabis industry.

Based on the WHO findings, CBD is safe and well tolerated in humans (and animals), is not associated with any negative public health effects and does not have the potential for addiction or abuse.

Medsafe should remove the classification of CBD as a prescription only medicine, which would immediately make it accessible, as a pharmacy only or over the counter – general retail product, depending on CBD content.

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:

MOH have to acknowledge that there is already a medicinal cannabis industry. Many patients are currently being supplied by individuals, green fairies and others via a black market for cannabis products.

If the scheme is too hard to be involved with many of these patients will continue to use the black market. And doctors will be put off as they will not know anything about how the product is used, why people are using it and what effect it is having.

Consumers/patients are already interested in obtaining access to the product. The prescribers will need to be educated so they are comfortable with the perceived and actual risks. The producers need to be enabled to provide full plant spectrum products, and blended products from extracted API and the naturally occurring biomass.

International companies will enter the market quickly and this competition seems to be the main policy for MOH to achieve their objective of affordable product. This will reduce the ability of New Zealanders to be part of the economic potential as they will take time to achieve compliance.

To achieve an equitable outcome New Zealand companies will need to be enabled and have access to local markets for unapproved products and export markets for bulk commodity based materials.

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:

Our members are interested in cultivating industrial hemp for medical purposes and we already have a licence that allows us to grow low THC crops, our cultivation and harvest registers allow us to track areas or individual plants so we are able to comply with the reporting requirements of the Medicinal Cannabis scheme, our licence allows us to deal with a controlled drug and are therefore very similar to the licencees issued under the Misuse of Drugs Act.

We see no reason why biomass and plants grown under our industrial hemp licence can't be used as starter material for a medical cannabis manufacturer. As both controlled drug licences are so compatible, a medicinal cultivation licence should not be required to produce industrial hemp

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

The regulator is not in the best position to set cultivation standards.
The lack of understanding of what the consumer wants, and the requirements of the manufactures means any prescriptive levels put in place by the regulator would be a minimum standard and this would send the wrong message to industry, who have a higher level of self regulation.

The production of Medicines and non medicines have specific regulations that will need to be complied with, regarding the quality and safety of the labelled product required by consumers, therefore industry is best placed to ensure that compliance is done effectivity and efficiently.

Testing and checks are required by any manufacturer of medical and non-medical grade product. Depending on the end use there will be various applicable levels of compliance

required (Ie GMP Vs GPP, or other relevant legislation, food control plan, or accreditation, such as ISO) This will be informed by the requirements in the specification required by the customer, which the manufacturer will need to meet.

The licenced producer/manufacture is responsible for ensuring their products are compliant, as such they are in the best position to decide how this is best achieved.
A regular report to the Agency will provide the information necessary to complete our international treaty obligations.

A specification set by a manufacturer for the starter material will be sufficient to meet the quality requirements of their end products. The manufacturer is taking the risk and will naturally want to protect their considerable investment by ensuring compliance and that the finished product meets the required quality standard.

There should be no restriction set on the stater material as all parts of the plant can potentially be used, fresh or dried, in whole or lightly processed. It could be blended to give the desired full plant spectrum starter material or go into a primary processing step such as crushing or extraction to meet the manufactures specification.

Once the raw material meets the manufactures specification, the production process can begin, resulting in finished goods ready for labelling that meet the quality standards for the markets they are going to enter i.e. GMP for medicinal cannabis products or other international standards for non-medical products (nutraceuticals, natural health products and supplements) being exported.

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

Comments:

Imported medicinal and non-medicinal products will need to meet finished goods quality standards. MOH are unlikely to require the starter material on imported products to be tested, as it is covered by the compliance with the quality standard for the finished product.

The final testing of the product would be sufficient for overseas products to be allowed into New Zealand and we would need the same level playing field for our products developed in New Zealand

Our, best practices business approach would be challenged if the regulator put in place minimal standards, as it could reduce the level of compliance achievable as licenced producer. GAP already provide the guidelines and standards expected when growing crops, and would be complied with if required by the manufacturers specification

There is no reason for the regulator to be involved in the commercial process of setting standards for cultivation, they have no experience nor resources to take on this role. As it

is the manufactures responsibility to be compliant to the finished goods standards, they are the only people with a vested interest in ensuring all aspects of the value chain achieve compliance

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:
A is the only appropriate option and if the manufacturers specification requires NZ GAP this will become a requirement that the cultivator under a iHemp licence would need to comply with.

The main international markets will be for unapproved medicinal cannabis products and other non-medical products, which can be sold into markets where there is a legal framework to allow them to do so.

Many of these countries are signatories to the single convention and allow the production, manufacture, supply and export of cannabis supplements and nutraceuticals.

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:
We would have to canvas our members, but many ihemp farmers who want access to the revenue streams from the whole plant would consider harvesting biomass and plants for the medicinal and non-medicinal markets, including growing specifically for these markets.

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:
It should vary depending on the THC content.

To be in alignment with Australia, Medicines Control should increase the iHemp THC level to 1%, which would provide access to a wider range of potential cultivars suitable for medicinal use, this would help achieve the objective of better more affordable access for consumers and patients, whilst improving the economic benefits for New Zealand.

Using the current THC levels, under an industrial hemp licence, low THC >0.35% iHemp will be grown in "safe" locations at all these levels depending on the growing approach from broad acre arable farming down to the market garden regime of individual plant husbandry

For plants with a THC content between 0.35%-2% these also might be grown outdoors and the slightly higher THC content, may lead to an increase in the perceived risk of diversion. Therefore they may need to be grown in more secure areas where access can be further restricted, via geographic isolation, or other environmental features such as

hidden behind other crops or hedge rows or fields only accessible past the farm house through locked gates.

Cultivators of higher THC crops 2%+ would need to provide further security which may involve the above, plus things such as fences, access control and cameras depending on the grower and their location. Depending on end use these higher THC crops will likely be grown indoors which would give the licencees more opportunities to increase security and restrict access.

No licencee wants to lose any crops. Therefore, industry has a high interest in stopping any potential diversion and will put in place controls to reduce and manage this risk.

As with the industrial hemp regulations any losses would need to be reported.

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

Comments:

New Zealand GAP is sufficient, as all starter material will have to meet the specification set by the manufacturer, so there is no need to go further than GAP, as MOH are not qualified to set further standard and there is no need to reinvent the wheel when suitable agricultural standards exist.

The Medicinal Cannabis Scheme will need to have a similar provision as S67 of the industrial hemp regulations that ensures compliance with other regulation, acts and codes – This saves a lot of trouble as all these requirements are built into the industrial hemp regulations and are similarly not required to be individually included in the medical cannabis scheme.

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:
Medical products must be manufactured to GMP standards
Non medical and unapproved medical products can be produced faster under GPP standards and still provide the same level of safety and confidence for the prescribers. Therefore a combination approach would allow the industry to get underway quickly and provide a pathway for manufactures to become GMP certified or remain as GPP depending on the market for their medical and non-medical products.

Access to the export market for products is essential for our local industry to scale, thereby providing affordable products to NZ patients.

This would increase equity as the additional GPP pathway would allow NZ companies to export and create revenue to fund the building of capacity to produce affordable cannabis based medicines.

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:

GMP is the required standard to produce medicines under the Medicines Act and will likely be required for exports of medicinal cannabis product to most jurisdictions.

The Scheme will need to confirm that in accordance with the NZ version of GMP, the GMP standard begin after the extraction or primary processing of the starter material.

Unapproved medicinal cannabis products can be produced to GPP and still meet the specification of the manufacturer/customer, this would allow these produce to enter the market quicker and allow the industry to scale knowing they can sell the product in export markets which will improve access to affordable products for local consumers

Non-medical cannabis products (which are covered under the iHemp regulations) nutraceuticals, natural health product and supplements can be produced and marketed internationally, therefore do not need to meet the GMP standards in the Medicines Act.

We feel these products can be manufactured and immediately exported to many international markets under existing quality standards. Extraction from industrial hemp biomass, is a "process" and should be allowed under our industrial hemp licence. The export of extracts, finished product and raw biomass should be available under the existing industrial hemp regulations.

With only raw cannabis/biomass or THC extracts requiring an export permit as all other products are "hemp products" derived in whole or in part from industrial hemp

These non-medicinal products would not need dose information, but rather have accurate labels disclosing the amount and concentration of the API's so the consumers can make informed decisions

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:

The final products must meet the manufactures specification and comply with the quality standards so the consumer is protected.

To achieve the objectives and be equitable New Zealand manufactures will need to move quickly to compete with the overseas products, which will be immediately available in NZ.

Allowing GPP will support equitable health outcomes, by ensuring product is available, it allows wider access to the economic benefits, especially for Maori and others who can use this as a stepping stone, to get underway, prove the business case and fund the building of the required infrastructure, and protocols to comply with GMP

By achieving economies of scale quickly we can use the income from overseas markets to make product, available to the local market at an affordable price

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:

We acknowledge that approved medicines will need to meet the required quality standards as detailed in the Medicines Act

Unapproved medicinal cannabis products made from the leaf and flowering tops will not have to meet the GMP requirements, as they are not being sold as medicines.

This allows manufactures to immediately produce and export industrial hemp food, dietary supplements, natural health products and nutraceuticals in to overseas markets which allow and accept such products.

The use in the local market for these non-medical products may be problematic, if they are considered a " Food" as ANSFA will need to accept an application to amend the Food code to allow the whole plant as a food, not just hemp seed.

Industrial hemp supplements, nutraceuticals and natural health products should still be available within their own regulator frameworks and access will be improved when the medicines classification allow various OTC (over the counter) products and at other concentrations allow pharmacists to dispense them without prescriptions. Prescriptions could be for product containing THC.

It is important the regulator acknowledges that THC is what needs to be controlled, as this is the psychotropic compound and is the biggest risk driving diversion. Which is what the medicinal cannabis scheme has been set up to control.

A higher THC plant is no longer exempt under the Single Convention as it is no longer being grown for industrial or horticultural purposes, so a Medicinal Cannabis scheme is needed to simply provide licences that capture the reporting, information required and provide guidance to the relevant legislation that provides the larger framework within in which the medicinal cannabis industry will operate.

Done well medicines control will create enabling legislation allowing an industry to develop which meets the objectives; access, affordability, quality products, meeting consumer needs and providing equitable access to the economic potential of the medial and non-medical cannabis industry.

Given the safety of cannabis based medicinal products and the wide variety of uses, from functional foods to natural health products and products with therapeutic uses, the scheme will need to acknowledge the wide range of production processes required to meet these uses, all of which already have existing compliance frameworks.

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

Comments:
Yes, synthetic cannabinoids are not naturally occurring and cause most of the problems overseas so should be banned.

A distinction needs to be accepted between non-medical products and medical products, if we are not making medical claims then full plant spectrum products made from naturally occurring industrial hemp are hemp products and should be made available under the industrial hemp regulations as supplements, nutraceuticals or natural health products.

Un-approved and non-medical products would **not** need to be produced to GMP standards, GPP standards will be quicker to achieve. The smaller international markets for prescription only medicinal products would require GMP. Allowing both options gives licenced producers the flexibility to adopt the most appropriate approach, given their capital resources and business plan

Given the WHO and other organisations recommendations that these (especially CBD) products are safe and show no signs of potential for abuse then patients in need should have access to these products, in various forms suitable to the health outcomes desired.

The significant paranoia from 80 years of prohibition have misinformed the regulator and public who are missing the importance of this natural medicine and the benefits and safety it provides. Which is now being acknowledge by the global demand for medicinal cannabis products

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:
Both approaches will increase the cost, so it is important that manufacturers have access to the export market as soon as possible so they can start generating income to offset these costs, this cashflow will allow industry to scale and give us a level playing field to compete with imported products. This will increase access to quality/affordable products for the patients in New Zealand.

If we can only make APIs at very small levels for the local prescription only market the costs will be excessive, due to small production runs, which will make us uncompetitive with imported products who are already manufacturing at scale

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:
Depending on scale and the customers they want to service, companies will adopt a range of approaches to manufacturing, these will involve consideration of investment required and how best to meet the requirements of global markets while also servicing New Zealand based patients and consumers

Limiting manufacturers to GMP, will not achieve the schemes objectives and is unnecessary as not all medical cannabis products will be used as approved medicines.

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:
As discussed previously, this approach allows the industry to work with a wider range of starter material which is in demand in many export countries which we can access quickly while we fund the development of other medicinal cannabis products. This creates the level playing field we need to get started and complete with imported products.

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:
Following consumer demand, we anticipate making a wide range of medicinal and non-medicinal products that comply and meet the customer specifications in local and export markets

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:
Efficiencies come with economies of scale, small production runs are always more expensive, so we need to have access to markets that will allow us to scale up production and share the cost of production over a wider number or range of products.
Then the savings from these efficiencies can be passed on the consumer, this could be a factor of 20x cheaper when operating at scale

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:

GMP Standards should only apply at the level of final manufacture, labelling and packaging. Prior to this, the starting material/API, will be tested to insure it meets the manufactures specification. This is in alignment with the NZ version of GMP

This may require the "Manufacturing licence" to have another "primary processing level licence", to cover the contract extractor or processor. To allow them to process cannabis plant material (as a controlled drug, in their facilities). These processors do not need to be GMP certified as they are already compliant with Food Control Plans, ISO or other accreditation suitable for the processing they do.

The product they produce must meet the spec of the manufacturer and this is when the requirements of a GMP process should begin

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:
To be useful all API's will need to be manufactured to the specification of the manufacturer, or overseas buyer, these specifications will require compliance with a quality standard, so this is business as usual for the extraction company or those involved in producing the API.

As the specification is set by the manufacture, the requirements for GMP start at this point, if the starter material or API meets the specification, it is good to begin the journey through the manufactures GMP process to become a medicinal cannabis product.

If the end product is a prescription medicine then the New Zealand Product Quality Standard monograph is appropriate

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

Comments:
Prescription medicines and pharmaceuticals must comply with this level of validation and stability testing, by making medicinal claims you need to comply with the medicines act and associated GMP and API standards for your medical products

Non-medical products do not require the same level of compliance and the quality is determined by the end consumer and the compliance frameworks in place in those export or local markets

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:
Approved medicines which have gone through the entire medical process will be able to comply with the need for dose information on the label.

Unapproved products will not have had the same level of due process, so the information provided to the prescriber will need to reflect the levels of active ingredients and guidelines for prescribing, as every patient is different, starting low and going slow is the mantra, until the patient finds the sweet spot for the best therapeutic dose for them

Dose information will not be relevant for non-medical and food uses in export markets where these types of products are allowed. Compliance will be achieved with appropriate labelling describing the content of the API

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?
What ever works for the individual patient at that time, to treat the condition they are suffering from should eb available

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

Comments:
Inhaling cannabis is the quickest way to get through the blood brain barrier and should be an acceptable form of administration. Raw cannabis flower is the least costly form of medical product and can easily be tested to ensure only naturally occurring cannabis is present. Establishing doses for unapproved medicines will be difficult and inhaling is a useful way of controlling and establishing relevant dosage for individual patients
The political treatment of tobacco should not automatically flow through to other smokeable products if there is no / limited harm

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:

This would be appropriate for approved medicinal cannabis products available via prescription only. This would be different for unapproved products which have not been assessed or manufactured at this level. Non-medical products would need to comply with other legislation, i.e Food Act, National Health Product Act or other compliance frameworks

As prescribers will need to have confidence to prescribe, they will need to be working closely with industry and patients to ensure that finished goods are available that meet the required quality standards for the particular use. Which will depend on the status of the product, consented, unapproved, and the manufacturing process.

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:
This would be normal for all API and finished products in this sector both medicinal and non-medicinal should be able to be traced to the originating manufactured batch, for traceability and transparency and in case of product recalls, this is best practice and will be a normal requirement for industry

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:

Industrial hemp licences need to be accepted for low THC Crops (see Q49)

Security should be relative to the THC content of the plants being grown, a safe location will be sufficient for industrial hemp as per the industrial hemp licence requirements.

Whereas higher THC will require additional controls, these security features should be as a requirement of the commercial operation ie cultivation, primary processing and manufacturer. The controls in place should be set up to reduce or eliminate the risk of diversion and the voluntary compliance approach of the company should be sufficient to meet the needs of the licence application.

There is no commercial gain in the medicinal cannabis scheme prescribing what "secure" means as each application will be different and should be considered on a case by case basis, with consideration given to the controls put in place which are operate to the operation in the value chain they are involved with.

Given the significant cost of the licences, a pre-review should be done before an invoice is issued, this would ensure only application likely to be successful are considered.

Or a refund scheme put in place, which refunds the application money (or some of it) if the application fails early in the process, before much work has been done.

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:

The discussion about what is reasonable with regard to security should be based on the merits of each location and applicant and with regard to the licence they are applying for, as the risk of diversion might be less or more in some cases depending on how involved they are in the value chain and what other internal controls are in place to reduce the risk of diversion and to identify if it has occurred.

There is a difference between a primary processor who may process some starter material for a day or two compared to a cultivator who is growing continually. Or a product manufacture who is responsible for quality standards.
All food and medical grade products have to comply with many levels of control, all of which help to keep the ingredients/products safe and secure.

High licence costs will be a barrier to entry for some applicants, who could otherwise comply with all other licence requirements. These applicants should not be deprived of a licence to participate in the economic benefits of the NZ industry simply because of the high cost of the licence

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:

Our industrial hemp general licence allows us to grow the controlled drug, low THC industrial hemp.
Our farmers want to access the revenue streams from all parts of the plant.
If our biomass meets the medicinal cannabis manufactures, specification we should be able to supply it into this market.

We believe our low THC biomass and plants should be able to be extracted to produce export quality API and finished products in the non-medical nutraceutical, supplements and natural health products markets in international jurisdictions where it is legal for them to import.

We disagree that low THC industrial hemp when made into these non-medical products should be controlled by the medicinal cannabis scheme, it does not make sense as we are not making medicinal claims and there is already frameworks for us to produce these hemp products. And export jurisdictions able to import them

Given the intent of the industrial hemp regulations was to enable an iHemp industry, then naturally occurring amounts of various cannabinoids, terpenes and flavonoids, cannot prohibit industrial hemp products from being manufactured and sold into markets where they are allowed.

The one molecule triggers MODA is not a relevant argument, because following this through to the logical conclusion we would have to accept we do not have a hemp industry, which is clearly not the case, as MOH continue to issue industrial hemp licences.

If the medicinal cannabis scheme wants to have access to affordable cannabis medicine (both approved and unapproved) then you will need to allow iHemp grown under a hemp licence to be transferred in to the medicinal scheme. We can meet the manufactures/customers specifications for starter material, produced under GAP or GMP and are ready to supply the market this season, allowing quicker access for medicinal products.

It would be seen as a revenue gathering exercise if a industrial hemp grower was required to obtain a further medicinal cannabis licence to cultivate iHemp, it would come at a considerable cost and add no benefit from a diversion or quality standard point of view. It would simply be a high compliance cost which would have to be passed on to the manufacture and then the consumer.

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:
Yes assuming all licence requirements are complied with. Both the MODA licence and the industrial hemp regulations licence allow the holder to work with a controlled drug, the application process and licences are very similar and both industries need access to quality seeds

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:
Until approved they would have to be under a iHemp research and breeders' licence, but assuming all compliance requirements have been followed this would be just another source of low THC industrial hemp seeds for the R&B program for the licencees.

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:
The licences should be relative to the strength of THC being grown, the relevance of a small or large area is questionable and the sizes given seem arbitrary and do not have much correlation to what the cultivators are likely to want to grow.

iHemp growers cultivating under a iHemp licence should not need a medicinal cannabis licence as a are already authorised to grow low THC iHemp

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:

If seed has been used in New Zealand for a long period of time then it is acclimatised and may be of interest in a breeding program, for either low THC iHemp or a higher THC medicinal cannabis program.

If this system is encouraging the import of cannabis seeds, so individual NZ growers can claim them as their own intellectual property, then this is a biosecurity issue and should not be encouraged.
There is an import health standard for seeds for sowing and this covers Cannabis seeds.

As the industry develops and gains credibility there will be other illicit growers who may come forward, so allowing them to do so in their own time, would be preferable to imposing a deadline, as this might stop these people from coming forward when they are ready to do so.

No limits on declarations should be put in place as access to local varieties could be an important source of genetics for both the iHemp and medicinal cannabis industries

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:

This will slow down the speed to market for local manufactures. However if allowed it would only benefit some companies which may not be considered equitable to the other companies involved.

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:

See answers to question 47 and 48

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

Assuming this relates to a full licence to supply, the cost of the licence will adversely affect the availability and supply of CBD products, the high cost of product approvals will also adversely the objectives to make medicinal cannabis products available as these costs will need to be passed on to the consumer/patients

The current definition of CBD products will be difficult to achieve as other cannabinoids begin to be used in medicinal cannabis products

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:

Un-justifiably high licence costs will make medicinal cannabis products expense for consumers and patients, which will mean you will not meet the objective of making them affordable

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:

Un-justifiably high licence and compliance costs will make medicinal cannabis products expense for consumers and patients, which will mean you will not meet the objective of making them affordable

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

If the Medicinal cannabis scheme will not allow the export of unprocessed or bulk cannabis, then this is a restrictive business practice, which limits the potential revenue streams accruing from an export market which has the framework to accept cannabis in this form

It does not make sense to allow an industry and then to tell them they cannot export the raw commodity, clearly many companies will be wanting to vertically integrate and export higher value branded product in a final dose from, but others will need access to the bulk unprocessed market to achieve economies of scale.

From an equitable point of view there will be start ups (Particularly Maori) which do not have the investor base to achieve GMP level production quickly. These companies may still be involved by supplying unapproved product via a GPP system to local prescribers and patients, but this is a very limited market which would not require all the product they can cultivate, so having access to the commodity end of the export market as a starting point will provide cashflow for these companies to grow and develop approved medicinal cannabis products

As industrial hemp is not reportable under the UN single Convention the, ability to export low THC industrial hemp biomass should be enabled, and as long as the receiving country is allowed to accept raw industrial hemp then an export permit should be issued by MOH

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:

We will need to achieve economies of scale to support the objective of making medicinal cannabis products affordable, this will also require considerable cashflow which will not be forth coming if we do not have access to the revenue streams from all parts of the plant.

There is a large export market for medical and non-medical products, into jurisdictions who can accept raw controlled drugs or processed (extracted) products and finished goods, the industry must have access to these markets, while the domestic market works thorough the regulator process required to allow them to be consumed in New Zealand.

Other jurisdictions have already been through this process and will be importing their Medicinal Cannabis products in to New Zealand, our industry needs a level playing field so we can access international markets while we get registered under GMP to produce affordable medicinal cannabis products in New Zealand.

This level playing field for raw cannabis will be especially important for Maori and other organisations who are entering the market with limited capital, but who can scale and supply quickly

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:

Yes meeting or exceeding quality standards is the aim of our member companies involved, or looking to be involved in this sector.

It should be noted that the relevant quality standards should be linked to the type of product being produced, an approved prescription medicine will need to meet GMP, unapproved medicines manufactured under GPP, will have to meet similar quality standards but differing validation steps.

Non medicinal products will need to comply with other frameworks and standards in the importing countries jurisdictions, these may related to food and beverage standards or those associated with dietary supplements and natural health products

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:

Non medical cannabis products should not require a prescription, hemp products as functional foods, nutraceuticals, dietary supplements and natural health products are allowed in many of our export markets and we need to be able to supply these markets, to

generate economies of scale and cash flow to support the quicker access to cheaper medicinal products.

The New Zealand market will in time allow non-medical products, and they will not fit under the Medicines Act, so it is in appropriate to classify these hemp products as prescription only medicines when they are actual functional foods, or natural health products.

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:

Specialists should not be required, this is an unnecessary step, which creates more cost, with little if any benefit as medical practioners are already able to prescribe controlled drugs

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:

The medical professional is in the best position to evaluate if off label use is appropriate and this ability should be available to them when prescribing MC products, without requiring the involvement of a specialist

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:

To achieve the objectives of the scheme and allow products to enter the market quicker, then the less the Ministry of Health is involved the faster the process becomes.

By leaving the decisions to medical professionals and the industry, compliance with the objectives will be ensured as they are controlled and licenced by the scheme and associated relevant legislation

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:

Specialists should eb allowed to prescribe medicines they consider fit for purpose.

Given the work load required to administer the medicinal cannabis scheme, MOH simply do not have the resources to approve unapproved medicinal cannabis products.

This will limit the objective of providing equitable access to affordable medicines. The formality of requiring Ministry of Health approval will unnecessarily delay the process and will add nothing to the requirements of safety and quality which would have been confronted by the manufacturer and the specialist. These unapproved medicines would be very much on a case by case basis and would natural involved the Medicinal Cannabis Agency throughout the licencing process, this would give adequate opportunity for the Agency to address any concerns

The other requirements of the MC scheme and associated legislation and frameworks will provide the compliance required to control unapproved MC products.

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:

This is a missed opportunity to help New Zealanders achieve optimal health and does not support the objectives of the scheme, please see 85 below.

The definition of a CBD product is to narrow and ignores the relationship to other cannabinoids. We need to be clear the motivation for all of this legislation is to control THC as a psychotropic drug, if the 1975 Misuse of Drugs Act had been worded better, we would be concentrating on the THC Delta-9-Tetrahydrocannabinoid as the only

cannabinoid with psychotropic effects, the other cannabinoids, seeds and plant material would not be mixed up in this need for higher levels of control.

Therefore, CBD when used as a supplement does not need to be a prescription only medicine, it is one of many naturally occurring cannabinoids, flavonoids and terpenes that are naturally occurring in hemp that has traditionally been used throughout human history as a functional food and source of fibre.

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:

CBD products should be reclassified and removed from being only a prescription medicine. Medicines Control should take the lead on this process, to allow a wider range of cannabinoid based, medicines and non-medicines to be made available to patients and consumers.

The control should only be put on the controlled drug THC, as CBD has been proven to be safe and not associated with any negative public health effects (WHO Report)

At various concentrations/doses it should be allowed as a functional food or over the counter product, and when used with THC a pharmacy only product or prescription medicine containing a controlled drug.

This would lead to the most equitable outcomes for access to product and will relieve the pressure on the public health system as the population would be healthier as a result of using hemp as a functional food, natural health products, dietary supplement or nutraceutical.

Allowing the population access to phyto-cannbinoids will improve the effectiveness of New Zealanders endo cannabinoid system, which will support their immune systems to fight diseases and inflammation whilst maintaining the body's natural homeostasis (balance)

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:

No, they are at different levels in the approval hierarchy, some unapproved medicinal cannabis products may go through the clinical study process to become approved drugs

But given the safety profile of cannabis many others will likely remain un-approved, as they have entered the market and if they meet the needs of consumer then they will be preferred, the confirmation provided by clinical studies will be irrelevant to the consumer/patient who is only interested to know if it is effective for them.

Clinical information helps prescribers and specialist to gain confidence that a particular approved product will be useful in a particular case

Given the wide range of uses for medicinal cannabis products, prescribers can have confidence in the effectiveness due to sources other than results from clinical trials.

Natural products, such as Cannabis medications require a more tailored approach to the individual patient, to see what works for them. For example, the rule of thumb is start low and go slow, when looking for the appropriate dose level, as is you don't find that persons "sweet spot', the medication may become less effective at higher or lower doses.

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:

Yes, it seems obvious that medicines will need to comply with the Medicines Act

However non-medical products should not be expected to have to comply, if they are covered by other legislation such as the Food Act/code or Natural Health Product regulations, these frameworks will provide the after market procedures required.

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

Comments:

It seems that post market monitoring for medicines and consumer products is adequately covered by the Medicines Act, Consumer Guarantees Act and other legislations, such that these frameworks are not required to be spelt out in detail in the MC Scheme, a simple acknowledgement in the Scheme would be sufficient to highlight the need to comply with post market monitoring and compliance, as per the relevant frameworks and legislation

Industry will naturally want to work closely with consumer/patients and prescribers to ensure they are supplying useful product customers want, that meet or exceed compliance and quality standards

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:

The Agency will need to have a budget to achieve the 3 abilities above, which will be required as a reaction to a problem in the cultivation and manufacture value chain with regard to supply of quality product.

A process for reporting issues will be required and the agency will need to promote and encourage customers/patients and prescribers to use them.

This does not help the other objectives to support the prescribers and consumers/patients with information around what compliance looks like, what are the qualities expected of medicinal cannabis products and how are they prescribed and distributed - A budget will be required to raise this awareness, which will mitigate the enforcement issues, if everyone know what to expect from the level playing field created by the MC scheme.

As with the iHemp regulations, there will need to be procedures in place in the legislation to follow if a recall, complaint etc has resulted in the amendment/cancellation of a licence, as there maybe other information not available at the time to the regulator which should be considered when deciding on a particular action plan, the licencee must be given the right to reply

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:

- What do the consumers and patients want
- How are medicinal cannabis products being used, both those available through the MC Scheme and from the black market
- Data on the effectiveness or not of the products used, at what levels (doses/concentrations/frequency) and over what period of times
- Collection of rower and manufacture information to meet international reporting requirements
- What additional information is required (or would be useful in the clinical proposal) by doctors when prescribing MC products
- Documenting adverse reactions and any affects with other medications.
- If synthetics are allowed, information on problems and adverse effects from this source should be kept separate from any that are reported from natural cannabis

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:

Yes, the fees as recommended will make it expensive to work with all aspects of the value chain for medical and non medical products, from the breeding programmes which for low THC crops can be done under a iHemp licence and for those cultivators wanting to work with higher THC plants, can do so under their cultivation licences.

But the high licence cost will be a barrier to entry for independent breeders (not cultivating/manufacturing) who are interested in this research and development space. These entities maybe working with some of the medicinal cannabis companies but if they are at a different location, then the licence cost may be duplicated.

Consideration needs to be given to allowing multiply sites under one licence for R&D and cultivation/manufacturing purposes

The costs for a manufacturer/supply/product assessment licence will be a barrier to entry for people wishing to do clinical trials, or evaluation/testing in labs which are not covered by a medicinal cannabis companies licence. Again the issue of multiply sites is a problem, as often various steps/operations are required which could involve many different locations and degrees of control while at these locations

The manufactures licence needs to eb split to reflect the pre and post GMP requirements and the processing they involved, a "primary processors" licence could cover initial processing such as extraction, and then the final manufacture and labelling could be covered by a "Producers manufacturing " licence

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:

The Fee structure needs to reflect the number of licences received and must be related to the type of cannabis being grown, low THC industrial hemp has a licence fee of $511.11 including GST, so a MODA cultivation licence for $16,800-$23,200 for low THC hemp cannot be justified.

Higher THC crops, may require more work in the review of the licence application and additional audit/validations, but again it is hard to see how a $23,000 fee is justified.

We are also concerned that the MOH do not have the resources to handle both the industrial hemp licences and the medicinal cannabis licences, so they will need to ensure the agency has sufficient staff to be able to handle the workload.

The agency and fee structure will need to include provision for various forms of both indoor and outdoor growing operations, which will have differing security requirements based on level of THC being grown.

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

Comments:

The administration of the Industrial Hemp Licences should be moved from control by Medicines control to another Ministry, to allow the Medicinal Cannabis Agency to concentrate on the medicinal cannabis scheme.

Which is more appropriate to MOH who have no knowledge of arable crops and are not suited to the issues of farming/growing iHemp

When used as a started material for medicinal cannabis product, iHemp grown under GAP will only be accepted by a manufacturer if it meets their requirements, so compliance and control is inherently built into the value chain for New Zealand producers