MEDICINAL CANNABIS AGENCY

MANATŪ HAUORA
MINISTRY OF HEALTH

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19 January 2024

Nikau W

By email: fyi-request-24970-e0c2c685@requests.fyi.org.nz
Ref: H2023033298

Tēnā koe Nikau

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 1 December 2024 for information regarding medicinal cannabis. You requested:

> "*I hear you have recommendations for the govt around medical cannabis law. Can you share any of the documents you have related to that and what those recommendations are*."

On 17 January 2024, the Ministry contacted you to clarify what specific information you are seeking regarding recommendations for the government around the medicinal cannabis law.

Your clarified request, received on 19 January 2024, is copied and responded to below.

> *1. Any and all briefings to the incoming minister of health that pretain in any way to medicinal cannabis.*

The Ministry has identified one mention of medicinal cannabis in the Briefing to the Incoming Minister (BIM). This is in Appendix A of the BIM outlining upcoming decisions in early 2024 within the health portfolio.

The Cabinet Paper (Legislation Committee): Amendments to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 is listed with a timeframe for decision being February 2024.

No other documents or communications from the Ministry to the Minister of Health have been identified. The full BIM will soon be proactively released on the Ministry's website at: www.health.govt.nz/about-ministry/information-releases in accordance with section 18(d) of the Act.

> *2.the current draft of new regulations*

The current draft of the amendment regulations are withheld under section 9(2)(g)(i) of the Act to maintain the effective conduct of public affairs through the free and frank expression of opinions by or between or to Ministers of the Crown or employees of any public service agency. A final draft may be available for release at a later date.

3.the application to treasury for exemption from regulatory impact analysis of proposed changes to medicinal cannabis regime.

The requested document is appended to this letter and has been released to you in full.

4. Any and all briefings or recommendations provided to the minister of health and or cabinet pertaining to medical cannabis for the period may 20th 2023 untill october 1st 2023.

This information is publicly available on the Ministry of Health website here: www.health.govt.nz/about-ministry/information-releases/release-ministerial-decision-making-documents/cabinet-material-improving-medicinal-cannabis-scheme-better-support-economic-and-research. Copies of the proactively released Cabinet material, on 'Improving the Medicinal Cannabis Scheme to better support economic and research opportunities' can be downloaded from this page.

If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Derek Fitzgerald
Licensing Authority
Medicinal Cannabis Agency

Proposed changes to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019

	Proposed change	Description	Exemption ground	Exemption rationale
1	Clarifying what 'ingredient' and 'product' refer to in the active ingredient definition.	'ingredient' refers to active ingredient and 'product' refers to medicinal cannabis product.	Technical clarification to active ingredient definition in the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Regulations) to improve clarity.	• Minor impact expected for businesses and individuals. • No expected financial impact.
2	Clarifying starting material interpretation to provide clarity for when cannabis is considered either starting material or a medicinal cannabis product.	'starting material' is intended to be further processed.	Technical clarification to the starting material definition in the Regulations to improve clarity.	• Minor impact expected for businesses and individuals. • No expected financial impact.
3	Allow medical practitioners to import medicinal cannabis products that do not meet the minimum quality standard for named patients.	Aligns with section 25 of the Medicines Act 1981 which allows medical practitioners to import unapproved medicines for a named patient.	Technical adjustment which provides for alignment with existing legislative provisions under the Medicines Act 1981.	• More enabling to align with section 25 of the Medicines Act 1981. • Minor impact expected on businesses and individuals and only confers benefits to medical practitioners who are involved in importing medicines. • Aligning with provisions currently allowed under section 25 of the Medicines Act 1981.
4	Exempt testing of container material, excipients, and other ingredients to be carried out at a Good Manufacturing Practice	In some situations, cannabis-based ingredients are not being sold or distributed. It is reasonable for	Technical adjustment to the minimum quality standard.	• This current requirement is inconsistent with the regulation of other medicines and expected practice. • Minor impact expected for businesses and individuals.

	(GMP)-certified manufacturer or laboratory.	container material requirements to not apply.		• Confers only benefits to industry who conduct testing. • No financial impacts expected.
5	Allow non-critical tests to be completed at ISO/IEC 17025 (ISO) accredited sites instead of being required to be completed at a GMP manufacturer or GMP laboratory only.	Better reflects the laboratory testing capabilities in New Zealand to support local products entering the domestic market.	Technical amendment to change the laboratory accreditation requirements for some testing to better reflect New Zealand testing capability.	• This does not impact on the overall quality of products supplied to New Zealand patients. • This better supports the domestic production of cannabis-based ingredients and medicinal cannabis products. • Confers benefits to industry and no financial impacts expected.
6	Amend the labelling requirements to include a reference to the Misuse of Drugs Regulations 1977.	Clarify that controlled drug classification statements take precedence over classification statements required under the Medicines Regulations 1984.	Technical adjustment to improve the clarity of the Regulations.	• Minor impact on businesses and individuals, as this is a descriptive change outlining what the current legislative provisions should be.
7	Expressly state in the Regulations that possession of cannabis is allowed only for the purposes of performing licensed activities.	Better clarifies the intent of this regulation.	Minor technical change to provide clarity and ensure consistency between the objectives of the Regulations and the required activities enabled to achieve these objectives.	• Minor impact on businesses and individuals.
8	Remove the reference to producing or manufacturing a cannabis-based ingredient or medicinal cannabis product under a medicinal	Helps better reflect the intent of research activity – for the purpose of clinical trials. This function is already enabled under a	This is a technical change to clarify the purpose of this activity.	• The research activity was intended for clinical trials only. • Minor impact expected for businesses and individuals. • No financial impacts expected.

	cannabis licence with a research activity.	possession for manufacture activity, which is the more appropriate authorisation.		• There is currently no medicinal cannabis licence holder with a research activity. Any research relating to producing or manufacturing a cannabis-based ingredient is already enabled under a different licensed activity (possession for manufacture).
9	Include testing of starting material and cannabis-based ingredients under a possession for manufacture activity.	The activity allows for testing of cannabis and medicinal cannabis products already. It is reasonable to extend this to starting material and cannabis-based ingredients.	Technical adjustment to a licensed activity to clarify the activities enabled and required under the Regulations for testing and validation of cannabis-based ingredients.	• The activity currently allows for testing of cannabis and medicinal cannabis products but not the intermediate step (the cannabis-based ingredient). • Allows for commencement of required legislative provisions. • Net benefit to industry expected, with only minor impacts to business and individuals.
10	Testing will be expressly stated as an allowable activity under the possession for manufacture licence.	Testing is an important aspect of product development. It is currently listed as a permitted activity but not as a 'purpose'. This change is intended to improve clarity of what this activity is intended for.	Minor technical change to clarify the purpose of the possess for manufacture activity.	• Provides clarity to the current allowable activities under the Regulations. • Net benefits expected, minor impacts to businesses and individuals.
11	Provide greater flexibility to the type of documents applicants can provide to support their applications for a licence, whilst still requiring that adequate arrangements be made to	Remove an identified barrier (only accepting standard operating procedures) and enable other appropriate administrative documentation (eg,	Technical adjustment to regulation 32.	• This has been identified as overly restrictive and is more of an administrative change which will increase options for applicants. • Minor impacts expected to businesses and individuals.

	prevent risk of misuse for an unlawful purpose.	procedures or operations manuals) in applications for medicinal cannabis licences under the Regulations.		
13	Amend the dosage product assessment fee to be consistent with the assessment fees for cannabis-based ingredients and dried products.	The current dosage assessment fee in the Regulations is $13,400 excluding GST. This includes an assessment for cannabis-based ingredients and the final dosage products. Most manufacturers are using the same cannabis-based ingredient for multiple dosage products. The fee for a dosage product should only reflect the assessment of the dosage product only.	Minor technical adjustment which provides for alignment with existing legislative provisions.	• Provides clarity of fees for industry, confers net benefits only. • Minor impact on businesses and individuals. • Minor change to internal administrative processes. • Corrects a drafting error.
14	Providing clarification on recording requirements for cultivation.	Better clarifies intent of this regulation. Confusion regarding who 'holder of a licence' refers to in this regulation.	Minor technical change to improve the clarity of existing legislative provisions.	• Minor impact on business and individuals. • No expected financial impact.
15	Clarify that licence holders must keep records for any destruction of material	Better clarifies intent of this regulation, including requirements	Minor technical change to improve the clarity of existing legislative provisions.	• Minor impact on businesses and individuals. • No expected financial impact.

	under a nursery, research, possession for manufacture and supply activity	that destroyed material also needs to be recorded.		
16	Update the date for reporting of stocktakes consistent with other controlled drug legislation.	Ensures consistency between legislation.	Technical amendment to remove legislative provision which is inconsistent with the treatment of all other controlled drugs.	• Align with requirements under regulation 49A the Misuse of Drugs Regulations 1977 (31 December) for the stocktake of controlled drugs. • Minor impacts on businesses and individuals. • Minor change to internal administrative processes. • No expected financial impact.
17	Include a new regulation to reference the Misuse of Drugs Regulations 1977 advertising of controlled drug requirements.	These requirements also apply to medicinal cannabis licence holders. This will clarify the application.	Clarifying an area of current legislation.	• Providing clarification for the advertising requirements under regulation 50 the Misuse of Drugs Regulations 1977. • Minor impact on businesses and individuals. • No expected financial impact.
18	Provide clarification for when the minimum quality standard only applies to CBD products	The minimum quality standard only applies where the active ingredients and cannabinoids originate from cannabis and the CBD product is intended for a therapeutic use.	Providing clarification for the intention and implementation of the current legislation.	• Aligning with the purpose and objectives of the Medicinal Cannabis Scheme. • More enabling for industry as they understand what is and isn't captured under the Scheme. • Minor impact on businesses and individuals.
19	Prohibit personal importation of CBD products for personal use via mail or courier.	Clarifies the intent of regulation 4A of the Medicines Regulations	Provides for alignment with existing legislative provisions on CBD products.	• Aligning with the purpose and objectives of the Medicinal Cannabis Scheme to

				ensure there is consistent regulation of CBD products in New Zealand. • Minor impact on businesses and individuals. • No expected financial impact.
20	Allow travellers entering New Zealand to import CBD products on their person if it has been lawfully supplied and the quantity does not exceed a 3 month supply.	Ensure that lawfully supplied CBD products are permitted for travellers like other prescription medicines.	Adjustment to remove unintended restrictive legislative provision.	• Aligning and ensuring consistent regulation of all prescription medicines under the Medicines Regulations 1984 which are being lawfully imported into New Zealand. • Clarifies activities currently enabled under the law for all CBD products. • Minor impact on businesses and individuals. • No expected financial impact.
21	Enable CBD products to be named on appropriate licences.	Allow CBD products to be named on a licence to manufacture medicines and a licence to pack medicines if they have not been verified as meeting the minimum quality standard. However, if they are required to meet the minimum quality standard, then supply would still be prohibited unless the product is either verified, or being	Unnecessary barrier identified; this change ensures consistency with the objectives of the Regulations.	• The current regulation states that these 2 licences do not apply to CBD products unless they meet the minimum quality standard. However, a manufacturer needs these licences to manufacture the CBD products in the first place. The current regulation is not operationally sensible and is not functioning as intended. • Minor change to internal administrative processes. • Minor impact on businesses and individuals. • No expected financial impact.

		supplied as part of an approved clinical trial.		
22	Enable licences to operate a pharmacy to supply products verified under the Scheme.	Allow licences to operate a pharmacy to supply cannabis-derived CBD products which have been verified against the minimum quality standard, received consent for distribution under the Medicines Act 1981 or are imported and supplied pursuant to a prescription by a medical practitioner for a named patient.	Technical adjustment to improve the operations of the Regulations.	• This addresses a conflicting legislative provision impacting what can be supplied on a pharmacy licence, which has been identified as a barrier. • Confers net benefits only. • No expected financial impact.
23	Allow some flexibility for manufacturers in determining assay limits for active ingredients.	Better reflect what can be reasonably controlled in the manufacturing process. The current regulation is difficult to achieve, too restrictive in some circumstances and not appropriate for broad spectrum cannabis-based ingredients.	Minor technical adjustment within the minimum quality standard of the Regulations.	• Improves clarity and the workability of the requirements for industry. • Minor impact on businesses and individuals. • No expected financial impact.
24	Clarify that manufacturers are exempt from complying with container material requirements if their cannabis-based ingredient is	The container material requirements apply only when a cannabis-based ingredient is sold and distributed.	Technical adjustment within the minimum quality standard.	• Aligns container material requirements with manufacturing requirements for other pharmaceutical products produced under the Medicines Act 1981.

	being stored in a manufacturing facility for manufacturing into products.	This proposal will also broaden the types of material that would be acceptable packaging (ie, food safe packaging) to better align with how this requirement is managed for other medicines.		• Net benefits only. • Minor impact on businesses and individuals. • No expected financial impact.
25	Allow the use of excipients with monographs from the British Pharmacopoeia, United States Pharmacopoeia and Japanese Pharmacopoeia in dosage products.	Better aligns with requirements expected for other medicines and allows manufacturers to use a broader range of materials.	A technical adjustment to improve the workability of the Scheme.	• Enable more options in excipients allowed to be used in the production of finished products. • Net benefits for industry. • Minor impact on businesses and individuals. • No expected financial impact.
26	Allow manufacturers to determine when some testing for cannabis-based ingredients and medicinal cannabis products is completed.	The current regulation requires some testing to be completed in both the cannabis-based ingredient and medicinal cannabis product. In some circumstances, it is appropriate for this testing to be completed at only one stage. This will help streamline compliance and testing costs.	Technical change to clarify requirements under the minimum quality standard.	• The minimum quality standard specifies tests that must be completed for a cannabis-based ingredient and a medicinal cannabis product. Some of these tests are for the same parameters and manufacturers are having to perform the same test twice. This amendment will allow manufacturers to only perform some tests once depending on the best stage that the parameter can be managed. There is no regulatory benefit of having the same tests performed twice. • Net benefits for industry.

				• Technical change to the minimum quality standard itself. • Minor impact on businesses and individuals. • No expected financial impact.
27	Amend regulation 18 to include a list or criteria for pesticides that can be permitted to be used on cannabis crops.	The current regulation managing pesticides permitted to be used on cannabis crops is unworkable and effectively prohibits use of any pesticides on these crops.	Technical change to the minimum quality standard proposed.	• Enables the current regulation to function as intended to manage the risk of pesticide contamination in medicinal cannabis products. • Regulation 18 which controls the use of pesticides for medicinal cannabis is currently unworkable. The regulation needs to be amended to update the requirements to regulate which pesticides can be used on cannabis crops. • Net benefits for industry. • Minor impact on businesses and individuals. • No expected financial impact.
28	Allow inclusion of further tests, test methods and limits to be included into the minimum quality standard.	Increase the range of tests permitted under the Regulations where appropriate.	Technical change to the minimum quality standard.	• Enables a broader range of test methods that can be used by industry to test the quality of their products. • The current minimum quality standard specifies which tests and test methods that must be completed. • Improves the workability of the regulations. • Net benefits for industry. • Minor impact on businesses and individuals. • No expected financial impact.

29	Allow CBD products that have received ministerial consent to be expressly authorised on licences.	Regulation 45B unintentionally prevents the supply of consented CBD products. CBD products which have received ministerial consent do not need to meet the minimum quality standard. However, this conflicts with regulation 45B which requires only CBD products that have met the minimum quality standard to be authorised on licences.	This proposal is a technical change to allow the regulation to function as intended.	• The current regulations exempt CBD products that have received ministerial consent from needing to meet the minimum quality standard. However, another regulation requires that ONLY CBD products which have been assessed as meeting the minimum quality standard can be authorised on a licence. • Improves the workability of the regulations. • Net benefits to industry. • Minor impact on businesses and individuals. • No expected financial impact.
30	Update the referenced European Pharmacopoeia in the Regulations.	The 10.0 edition of the European Pharmacopoeia referenced in the Medicinal Cannabis Regulations has been superseded.	Technical change.	• Update the version of the European Pharmacopoeia for tests in the minimum quality standard. The version in the Regulations has been superseded. • Improves the workability of the regulations. • Net benefits for industry. • Minor impact on business and individuals. • No expected financial impacts.
31	Clarify that CBD products intended for clinical trials do not need to be verified as	Aligns the regulation of CBD products with regulation on other	Technical change to align with the regulation of clinical trials.	• Unapproved medicines do not need their quality verified before being used in a clinical trial.

	meeting the minimum quality standard.	medicines carried by travellers and used in clinical trials, as per the Medicines Act 1981.		• Minor impact on business and individuals. • No expected financial impact.
32	Clarify that the minimum quality standard only applies to goods being exported for therapeutic end use.	Allow exports of starting material that do not meet the minimum quality standard on a cultivation or possession for manufacture activity for the purposes of testing, analysis and research. Allow exports of starting material, cannabis-based ingredients and medicinal cannabis products that do not meet the minimum quality standard by a holder of a medicinal cannabis licence with a supply activity for the purposes of testing, analysis, manufacturing or research.	Technical change to clarify the applicability of the minimum quality standard.	• The minimum quality standard requirement is currently applied to all exports of starting material, cannabis-based ingredients and medicinal cannabis products regardless of the intent of export. This is a barrier for local cultivators and manufacturers wishing to access testing, analysis, manufacturing and research services overseas and not proportionate to level of risk. • Change will benefit licence holders and allow the Scheme to function as intended. Currently, there are limited testing and manufacturing facilities in New Zealand. Companies need to access overseas facilities in order to complete testing and manufacturing so products can be verified as meeting the minimum quality standard. • Minor impact on business and individuals. • No financial impact expected.
33	Allow medicinal cannabis seed to be exported on a	Broaden the materials that can be exported	Aligns with how cannabis seed can be supplied domestically under the	• Minor impact of business and individuals. Confers only benefits to those in working under the framework.

	cultivation or nursery activity.	under the medicinal cannabis scheme. Currently cannabis seed can be supplied domestically but cannot be exported under a medicinal cannabis licence.	Scheme and exported under the Misuse of Drugs Regulations 1977.	• The licensing framework already enables export of medicinal cannabis. This expands the types of material that can be exported. • No financial impact expected.
34	Re-defining scope of nursery activity to procurement and supply of cannabis seed only.	This will remove any reference to import and supply of cannabis plant. This will clarify the intent of the activity. Import and supply of cannabis plant should be authorised under a "cultivation" activity which is the most appropriate authorisation for this activity.	Technical change to the regulation to clarify scope of the activity.	• The Medicinal Cannabis Agency has only issued this activity for seed supply purposes. • Minor impact on business and individuals. • No financial impact expected.
35	Remove "to produce or manufacture a cannabis-based ingredient or medicinal cannabis product" as a permitted activity under a research activity.	This will clarify that the intention of the activity is for clinical trials. This activity is already permitted under a "possession for manufacture" activity which is the most appropriate	Technical change to clarify the intent of the research activity under a medicinal cannabis licence.	• There is currently no issued research licence so this change will not affect current licence holders. • Minor impact on business and individuals. • No expected financial impact.

		authorisation for this purpose.		
36	Broadening the types of plant forms that can be considered 'starting material' and 'cannabis-based ingredients'	The current permitted plants forms are restrictive and not consistent with the types of plant forms (eg, dried cannabis or extracts of cannabis) that can be used in the manufacturing process. If change is agreed to, the minimum quality standard will need to be updated to specify the testing requirements to address any quality risks for when dried cannabis is used as a cannabis-based ingredient.	Improving the definitions to better align with the manufacturing process for cannabis-based ingredients and medicinal cannabis products.	• Minor impact on businesses and individuals. • Confers only benefits to affected industry stakeholders. • No financial impacts expected.
37	Allow import of material that does not meet the minimum quality standard for the purpose of research.	The minimum quality standard is currently applied to imports of material that does not meet the minimum quality standard even though the imports are intended for analysis and research purposes and not for therapeutic use. This will clarify the application of the	Technical change to address barrier identified for research activities.	• Confers net benefits only and will allow for greater range of research activities to be undertaken domestically. • Minor impact on businesses and individuals. • No expected financial impact.

		minimum quality standard to these imports.		
38	Allow a licence to possess controlled drugs be issued for cannabis grown under the Scheme, starting material, cannabis-based ingredients, medicinal cannabis products and industrial hemp. Allow medicinal cannabis and industrial hemp to be supplied to holders of a licence to possess.	Correct a gap in the licensing framework to allow non-therapeutic research to occur with domestically sourced cannabis. The pathway was removed in the drafting of the Regulations to provide distinction in the regulatory frameworks that oversees cannabis activities in New Zealand. It is now clear that it is acting as a barrier for cannabis-based research to occur in New Zealand. Proposal will reinstate a licensing pathway for these activities as it will allow researchers to access domestically grown material instead of sourcing from overseas or growing their own.	Technical change to address barriers identified for research activities allowed under the Regulations.	• Provides only benefits. • Minor impact on business and individuals. • No financial impacts expected.
39	Custody of controlled drug requirements.	Requirements for the custody of controlled drugs also apply to	Clarifying an area of current legislation.	• Providing clarification for the application of custody of controlled drug

		medicinal cannabis licence holders.		requirements under regulation 28 the Misuse of Drugs Regulations 1977. • Minor impact on businesses and individuals. • No expected financial impact.