Te Kāwanatanga o Aotearoa
New Zealand Government

MANATŪ HAUORA
MINISTRY OF HEALTH

Minister of Health

Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024

17 September 2024

These documents have been proactively released by the Ministry of Health on behalf of the Minister of Health, Hon Dr Shane Reti.

Title of Cabinet paper:

- Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024

Titles of minutes:

- Report of the Cabinet Legislation Committee: Period Ended 28 June 2024 (CAB–24-MIN-0245)
- Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (LEG-24-MIN-0129)

Titles of briefings:

- Briefing - Cabinet Legislation Committee: Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (H2024040105)
- Briefing - Update on changes proposed to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (H2024037065)

Some parts of this information release would not be appropriate to release and, if requested, would be withheld under the Official Information Act 1982 (the Act). Where this is the case, the relevant sections of the Act that would apply have been identified. Where information has been withheld, no public interest has been identified that would outweigh the reasons for withholding it.

Key to redaction code/s:

- Out of scope
- S 9(2)(a) to protect the privacy of natural persons.

CAB-24-MIN-0245

Cabinet

Minute of Decision

Report of the Cabinet Legislation Committee: Period Ended 28 June 2024

On 1 July 2024, Cabinet made the following decisions on the work of the Cabinet Legislation Committee for the period ended 28 June 2024:

Out of scope

[redacted]

LEG-24-MIN-0129 **Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024** CONFIRMED
Portfolio: Health

Out of scope

[redacted]

Out of scope

[redacted]

Rachel Hayward
Secretary of the Cabinet

LEG-24-MIN-0129

Cabinet Legislation Committee

Minute of Decision

Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024

Portfolio **Health**

On 27 June 2024, the Cabinet Legislation Committee:

1 **noted** that regulatory barriers have been identified which are limiting economic growth of the medicinal cannabis industry in New Zealand and an unsuccessful local industry would ultimately be counterproductive to the objective of providing quality and affordable medicinal cannabis products for New Zealanders;

2 **noted** that, on 19 July 2023, the Cabinet Social Wellbeing Committee agreed to changes that improve the Medicinal Cannabis Scheme to better support economic and research opportunities [SWC-23-MIN-0089];

3 **noted** that the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (the Amendment Regulations) will give effect to the decision referred to in paragraph 2 above;

4 **noted** that section 105(1) of the Medicines Act 1981 requires that the responsible Minister be satisfied that consultation with such organisations or bodies as appear to be representative of persons likely to be substantially affected by the regulations has occurred before recommending the making of an Order in Council under section 105(1);

5 **noted** the advice of the Minister of Health that this requirement has been met;

6 **authorised** the submission to the Executive Council of the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 [PCO 25908/10.0];

7 **noted** that the Amendment Regulations will come into force the day after notification in the New Zealand Gazette.

Tom Kelly
Committee Secretary

Attendance (see over)

Present:
Rt Hon Winston Peters
Hon David Seymour
Hon Chris Bishop (Chair)
Hon Judith Collins KC
Hon Todd McClay
Hon Tama Potaka
Hon Simon Watts
Hon Brooke van Velden
Hon Nicole McKee
Hon Casey Costello
Hon Andrew Bayly
Hon Andrew Hoggard
Hon Scott Simpson, MP
Jamie Arbuckle, MP

Officials present from:
Office of the Leader of the House
Officials Committee for LEG

In confidence

Office of the Minister of Health

Chair, Cabinet Legislation Committee

Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024

Proposal

1 This paper seeks authorisation for submission of the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 to the Executive Council.

Policy

2 The Medicinal Cannabis Scheme (the Scheme) was introduced on 1 April 2020 through the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Medicinal Cannabis Regulations). The purpose of the Scheme is to enable the commercial cultivation and manufacture of medicinal cannabis and improve patient access to affordable, good quality medicinal cannabis products.

3 Since the Scheme was introduced, some unintended barriers within the Medicinal Cannabis Regulations have been identified, with Industry stakeholders indicating that timely regulatory change is necessary for a commercially viable industry to be sustained within New Zealand's small medicinal cannabis market.

4 On 24 July 2023, Cabinet agreed to changes being made to improve the Scheme. These changes are mainly technical amendments, with some policy decisions intended to support the local industry to produce products for both domestic and export purposes, which will not only benefit those patients for whom they are prescribed, but also support New Zealand's trade and economic objectives, and increase its research and innovation opportunities [CAB-23-MIN-0313].

5 The key changes include:

5.1 broadening the medicinal cannabis category definitions to better reflect the different types of material that can be used at different stages of the manufacturing process and ensure that Good Manufacturing Practice requirements are applied at appropriate stages;

5.2 changing the compliance requirements to meet New Zealand and other countries' standards for exports of medicinal cannabis, so New Zealand companies can access export markets more readily;

5.3 adding a licencing pathway for non-therapeutic research (enabling possession of controlled drugs (under the Misuse of Drugs Regulations 1977)) for research with cannabis plant material sourced from the Scheme or the industrial hemp framework.

6 Cabinet also agreed to some minor technical changes to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Medicinal Cannabis Regulations), Misuse of Drugs Regulations 1977, and Medicines Regulations 1984. These changes are to improve the operation of the licensing framework and update requirements of the minimum quality standard.

7 The previous Cabinet paper included a proposal for cannabis-based ingredients and medicinal cannabis products to be exported without a requirement to meet the minimum quality standard, provided they are manufactured in accordance with Good Manufacturing Practice, and the Medicinal Cannabis Agency is satisfied that the importing country has a regulatory authority overseeing the quality of medicinal cannabis [SWC-23-MIN-0089]. Subsequent internal consultation has indicated that the requirement to manufacture in accordance with Good Manufacturing Practice is a sufficient control over the quality of exported cannabis and further regulatory oversight is unnecessary. Therefore, the requirement that the importing country has a regulatory authority overseeing the quality of medicinal cannabis has not been included in the amendment regulations or the associated guidance and internal processes.

8 The Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 will give effect to these decisions.

Timing and 28-day rule

9 I am seeking a waiver of the 28-day rule on the justification that the amendment regulations will have little effect on the public, and any effects would only be positive.

10 The amendment regulations will come into effect on the day after they are notified in the New Zealand Gazette.

Compliance

11 These amendment regulations comply with:

11.1 the principles of the Treaty of Waitangi;

11.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993;

11.3 the principles and guidelines set out in the Privacy Act 2020;

11.4 relevant international standards and obligations;

11.5 the Legislation Guidelines (2021 edition), which are maintained by the Legislation Design and Advisory Committee.

12 There are no statutory requirements for the making of regulations by Order in Council under the Misuse of Drugs Act 1975 (including for the Misuse of Drugs Regulations 1977, the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 or the Misuse of Drugs (Industrial Hemp) Regulations 2006).

13 There is a statutory prerequisite for the making of regulations by Order in Council under the Medicines Act 1981 for consultation with such organisations or bodies as

appear to the Minister to be representative of persons likely to be substantially affected by the regulations. I confirm that this requirement has been met through engagement with stakeholders on the intended policy proposals and the draft regulations.

Regulations Review Committee

14 I do not consider there are grounds for the Regulations Review Committee to draw this instrument or regulations to the attention of the House of Representatives under Standing Order 327.

Certification by Parliamentary Counsel

15 The draft regulations have been certified by the Parliamentary Counsel Office as being in order for submission to Cabinet.

Impact Analysis

16 A Regulatory Impact Assessment was prepared in accordance with the necessary requirements and was submitted at the time that Cabinet approval was sought on the policy relating to the regulations. It has been published on the Ministry of Health website: [Regulatory amendments to improve the economic opportunities of the Medicinal Cannabis Scheme | Ministry of Health NZ].

17 The Treasury's Regulatory Impact Analysis team has determined that some proposed changes to the Medicinal Cannabis Regulations, Misuse of Drugs Regulations 1977 and Medicines Regulations 1984 are exempt from the requirement to provide a Regulatory Impact Statement on the grounds that they have no or only minor impacts on businesses, individuals, and not-for-profit entities. The exempt proposals are identified in Annex 1.

Publicity

18 The Ministry of Health and Medicinal Cannabis Agency will inform affected stakeholders of the changes once agreed to by Cabinet.

Proactive release

19 I intend to proactively release this paper subject to any necessary redactions under the Official Information Act 1982 and in accordance with Cabinet circular CO(23)4 once the amendment regulations come into effect.

Consultation

20 The following departments have been consulted on these proposals: the Ministry of Foreign Affairs and Trade, the Department of the Prime Minister and Cabinet, the Ministry of Business, Innovation, and Employment, the New Zealand Police, New Zealand Customs Service, the Ministry for Primary Industries, the Treasury, Pharmac, the Ministry of Justice, the Department of Corrections, the Ministry of Disabled People, and New Zealand Trade and Enterprise.

21 A small number of industry experts were consulted on a limited exposure draft of the amendment regulations.

Recommendations

I recommend that the Cabinet Legislation Committee:

1. note that regulatory barriers have been identified which are limiting economic growth of the medicinal cannabis industry in New Zealand and an unsuccessful local industry would ultimately be counterproductive to the objective of providing quality and affordable medicinal cannabis products for New Zealanders;

2. note that on 24 July 2023 Cabinet agreed to changes that improve the Medicinal Cannabis Scheme to better support the economic and research opportunities [CAB-23-MIN-0313];

3. note that the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 will give effect to the decision referred to in paragraph 1 above;

4. note that section 105(1) of the Medicines Act 1981 requires that the responsible Minister be satisfied that consultation with such organisations or bodies as appear to be representative of persons likely to be substantially affected by the regulations has occurred before recommending the making of an Order in Council under section 105(1);

5. note the advice of the Minister of Health that this requirement has been met;

6. authorise the submission to the Executive Council of the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024;

7. note that the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 will come into force the day after notification in the New Zealand Gazette.

Authorised for lodgement

Hon Dr Shane Reti

Minister of Health

Annex 1

Proposals that are exempt from the requirement to provide a Regulatory Impact Statement on the grounds that they have no or only minor impact on businesses, individuals, and not-for-profit entities. Please note that proposals 28 and 29 are not included in the final Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024.

Proposal:

1. Clarifying active ingredient definition
2. Clarifying definitions to provide greater distinction between starting material with medicinal cannabis product
3. Broadening the types of plant forms that be considered starting material or a cannabis-based ingredient, including an amended minimum quality standard to account for these changes
4. Clarify that medical practitioners can import medicinal cannabis products that do not meet the minimum quality standard for a named patient who has received ministerial approval
5. Clarify laboratory requirements for testing of container material and excipients (ingredient other than active ingredient)
6. Broadening the type of laboratories that can conduct some testing to align with New Zealand capabilities
7. Amend labelling requirements to better align with requirements for controlled drugs
8. Allow greater flexibility for testing limits for active ingredients
9. Amend container material requirements
10. Broaden excipients (ingredients other than active ingredients) that can be used
11. Reduce areas of duplication in testing in the minimum quality standard
12. Amend requirements for pesticide use on cannabis crops
13. Broaden the range of tests, test methods and limits in the minimum quality standard
14. Update the edition of the *European Pharmacopoeia* referenced
15. Clarify application of minimum quality standard to products not intended for therapeutic end use eg, testing, analysis, manufacturing or research
16. Allow import of cannabis-based ingredients and medicinal cannabis products without requirement to meet the minimum quality standard for the purpose of research
17. Allow export of cannabis seed to be a permitted activity on a cultivation or nursery activity
18. Re-define scope of nursery activity
19. Clarify that possession of cannabis under a medicinal cannabis licence is permitted for the purposes of performing licensed activities
20. Amend research activity to better reflect intent
21. Allow testing of starting material and cannabis-based ingredients under a possession for manufacture activity
22. Add testing as a purpose for possession for manufacture activity
23. Broaden the types of documentation that can be provided to support applications for a medicinal cannabis licence
24. Correct the dosage product fee
25. Clarify recording requirements for cultivation activity

26. Clarify recording requirements for destruction of cannabis, ingredients and products
27. Align stocktake reporting dates with the Misuse of Drugs Regulations 1977
28. Refer to advertising requirements under the Misuse of Drugs Regulations 1977
29. Refer to custody of controlled drugs requirements under the Misuse of Drugs Regulations 1977
30. Clarify application of the minimum quality standard to CBD products
31. Clarify licence requirements for CBD products that have received ministerial consent under the Medicines Act 1981
32. Amend licence requirements for CBD products so the regulation can operate well and function as intended
33. Allow a licence to possess controlled drugs to be issued for starting material, cannabis-based ingredient, medicinal cannabis products and industrial hemp, including allowing researchers to source medicinal cannabis from medicinal cannabis licence holders

Briefing

Cabinet Legislation Committee: Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024

Date due to MO:	29 May 2024	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	H2024040105
To:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
Simon Medcalf	Deputy Director-General, Regulation and Monitoring	s 9(2)(a)
Chris James	Group Manager, Medsafe, Regulation and Monitoring	s 9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Cabinet Legislation Committee: Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024

Security level:	IN CONFIDENCE	**Date:**	29 May 2024
To:	Hon Dr Shane Reti, Minister of Health		

Purpose of report

1. This briefing provides you with a draft Cabinet Legislation Committee paper seeking approval to submit the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 to the Executive Council.

Summary

2. On 24 July 2023, Cabinet (under the previous Government) agreed to changes being made to the Medicinal Cannabis Scheme to better support the economic and research opportunities of the New Zealand medicinal cannabis industry. Supporting our local industry is important so that access to quality medicinal cannabis products can continue for New Zealand patients.

3. The Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 will bring these changes into force on 2 August 2024, or on 5 July 2024 if the 28-day rule is waived.

4. This draft Cabinet paper has undergone departmental consultation, and a draft of the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 has been reviewed as an exposure draft by a small group of industry stakeholders.

5. Feedback from the domestic medicinal cannabis industry indicates that timely regulatory change is necessary for a commercially viable industry to be sustained within New Zealand's small medicinal cannabis market.

6. Due to the urgency of some of these changes, the Ministry of Health (the Ministry) does not recommend delaying bringing these amendment regulations into effect to account for any potential change to international monographs, anticipated in 2024.

7. In line with the urgency of these changes, and that they are likely to have little effect on the public, conferring only benefits, the Ministry is recommending that a waiver of the 28-day rule is sought to prevent companies withdrawing from the industry due to difficulties of commercial viability.

Recommendations

We recommend you:

a) **Note** that in July 2023, Cabinet agreed for changes to be made to improve the Medicinal Cannabis Scheme to better support economic and research opportunities — **Noted**

b) **Agree** to circulate the attached draft Cabinet paper with your ministerial colleagues — **Yes/No**

c) Either:

Agree to request that Cabinet waive the 28-day rule which will bring the Amendment Regulations into force on 5 July 2024 — **Yes/No**

or

Agree to not request a waiver of the 28-day rule which will bring the Amendment Regulations into force on 2 August 2024 — **Yes/No**

d) **Lodge** the draft Cabinet paper, with any changes, by 20 June 2024 for Cabinet Legislation Committee consideration on 27 June 2024 — **Yes/No**

e) **Agree** to the Ministry announcing Cabinet's decision (if it agrees) and to the release of this report, the Cabinet paper, and the previous report (Update on changes proposed to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019) on the Ministry's website in accordance with Cabinet Guide requirements. — **Yes/No**

Maree Roberts
Acting Director-General of Health
Date:

Hon Dr Shane Reti
Minister of Health
Date: 31/5/2024

Cabinet Legislation Committee: Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024

Background

1. The Medicinal Cannabis Scheme (the Scheme) was introduced to improve access to quality medicinal cannabis products for New Zealand patients.
2. The Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Regulations) commenced on 1 April 2020 and gave effect to the Scheme. The Regulations detail minimum quality standards and a licensing regime for medicinal cannabis.
3. Since the Scheme was introduced, some unintended barriers created by the Regulations have been identified which may hinder the growth and sustainability of the medicinal cannabis industry in New Zealand. These barriers have developed partly due to evolving business models in the medicinal cannabis sector.
4. Feedback provided to the Ministry of Health (the Ministry) from the medicinal cannabis industry has indicated that timely regulatory change is necessary for a commercially viable industry to be sustained within New Zealand's small medicinal cannabis market.
5. A briefing (H2024037065 refers) was provided to you on 19 March 2024 to provide an update on changes proposed to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019.

Cabinet has agreed to make changes to improve the Scheme

6. On 24 July 2023, Cabinet (under the previous government) agreed to regulatory and technical changes being made to the Scheme to better support the economic and research opportunities of the sector [CAB-23-MIN-0313].
7. The key policy decisions included agreement to:
    a. amend the definitions of 'starting material' and 'cannabis-based ingredient' to capture a wider range of cannabis plant forms
    b. enable export of cannabis seed under the Medicinal Cannabis Scheme
    c. remove the requirement to meet the minimum quality standard for exports of starting material
    d. remove the requirement for exports of cannabis-based ingredients and medicinal cannabis products to be verified as meeting the minimum quality standard prior to export if manufactured under Good Manufacturing Practice and they are accepted by the importing country
    e. allow a licence to possess controlled drugs (issued under the Misuse of Drugs Regulations 1977) to be issued to authorise non-therapeutic research activities using starting material, cannabis-based ingredients and medicinal cannabis products
    f. allow medicinal cannabis licence holders to supply starting material, cannabis-based ingredients, and medicinal cannabis products for non-therapeutic research activities
    g. re-define the scope of nursery activity to seed supply

h. make technical changes to improve and clarify the minimum quality standard requirements

i. make technical changes to licensing requirements to help provide clarification, improve operations of the licensing framework, and to align with existing requirements in the Misuse of Drugs Regulations 1977.

8. The manufacture of cannabidiol (CBD) products (as defined in the Misuse of Drugs Act 1974) is captured under the Regulations. However, as prescription medicines rather than controlled drugs, the products are primarily regulated under medicines legislation. Therefore, some amendments are also required to the Medicines Regulations 1984.

9. A further minor technical change, not specifically agreed to by Cabinet, has been made to allow for the export of cannabis plant material for propagation. Currently, cannabis plant material (cuttings, rootstock, tissue, and tissue culture) can be exported under a licence to deal in controlled drugs, but this requires the material to be transferred out of the Scheme.

10. This is a minor addition to the agreed policy decision to allow for the export of seed as it only changes the pathway for this activity (allowing export of plant material to occur under the Scheme) and the same considerations for export apply. Industry groups have been consulted on this minor technical change as part of the limited exposure draft consultation and have not raised any issues.

11. The Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (the Amendment Regulations) will bring these decisions into effect.

12. The most recent draft of the Amendment Regulations has been provided alongside this briefing. We are currently working on finalising the Amendment Regulations. Due to the desire to bring these changes in as soon as possible and the minimal changes (minor technical changes and addressing drafting errors) expected in the final version, the Ministry has determined that providing the current draft is appropriate for consultation purposes. The finalised version of the Amendment Regulations will be provided to you as soon as it is available.

13. A brief explanation of each amendment is provided in a table in Appendix 1.

Consultation

14. In December 2022, the Medicinal Cannabis Agency undertook targeted engagement with medicinal cannabis licence holders, the New Zealand Medicinal Cannabis Council (representative industry body) and testing laboratories on some proposed changes to the Scheme. Feedback largely supported the proposed changes that are detailed in the Cabinet paper.

15. Minor technical changes such as clarification, and alignment with other pieces of legislation, considered necessary to the functioning of the Scheme were not specifically consulted on.

16. The draft Cabinet paper and the Amendment Regulations to bring these agreed changes into effect have been consulted on with the following departments: the Ministry of Foreign Affairs and Trade, the Department of the Prime Minister and Cabinet, the Ministry of Business, Innovation, and Employment, the New Zealand Police, New Zealand Customs Service, the Ministry for Primary Industries, the Treasury, Pharmac, the Ministry of Justice,

the Department of Corrections, the Ministry of Disabled People, and New Zealand Trade and Enterprise.

17. A limited exposure draft of the Amendment Regulations was also shared with a small number of industry experts in accordance with Cabinet Office Circular CO(19)2: Attorney-General's Protocol for release of Draft Government Legislation outside of the Crown.

18. Feedback from the departmental consultation and the comments received on the limited exposure draft have been considered in drafting of the Amendment Regulations. Most of the feedback related to technical aspects of the Amendment Regulations and changes have been made as needed to ensure workability. The remaining feedback concerned the policy proposals initially agreed to by Cabinet and will be considered for future updates to the Scheme.

Ensuring quality of exports while minimising regulatory burden

19. Feedback from some industry stakeholders was that a quality standard is important to prevent the export of poor-quality cannabis and to manage reputational risks of the New Zealand cannabis industry. The potential export of low-quality products to countries with significantly lower quality standards may negatively affect New Zealand's reputation as an exporter of high-quality products.

20. In the previous Cabinet paper, the Ministry proposed to address these risks by only permitting exports of cannabis-based ingredients and products:

    a. manufactured under appropriate controls (i.e., Good Manufacturing Practice)

    b. where there is evidence that the importing country has accepted the goods (either through an import licence that has been issued or a letter from the relevant regulatory authority)

    c. to importing countries with established regulatory authorities that oversee the quality of medicinal cannabis.

21. Subsequent internal consultation has indicated that the requirement to manufacture in accordance with Good Manufacturing Practice is a sufficient control to prevent the export of low-quality products. Exporters of controlled drugs will still need to provide evidence that the importing country has accepted their goods. However, it is not appropriate or practical for New Zealand to assess the regulations of other countries.

22. Therefore, the restriction of export to countries with established regulatory authorities that oversee the quality of medicinal cannabis has not been included in the proposed changes to the Scheme or associated internal processes.

23. Countries, including those without established regulatory authorities overseeing the quality of medicinal cannabis, may also choose to continue to only allow the import of products which have been verified as complying with the minimum quality standard.

24. The Agency will circulate and publish statements specifying that cannabis-based ingredients and medicinal cannabis products will no longer be required to comply with the minimum quality standard prior to export if they are manufactured under Good Manufacturing Practice.

More updates to the minimum quality standard may be required later

25. The minimum quality standard will be updated by these Amendment Regulations to reduce duplicate testing and broaden the range of test methods that could be used to demonstrate compliance with the minimum quality standard. Requirements for container material will also be updated.

26. The European Pharmacopoeia has recently announced an official medicinal cannabis monograph that will be implemented from 1 July 2024. A monograph contains detailed instructions for identification, purity and other specific tests to limit the amount of undesirable impurities in a medicine such as medicinal cannabis.

27. Prior to these announcements, there was no internationally agreed quality standard for medicinal cannabis and jurisdictions, including New Zealand, have been required to set their own standard.

28. Based on feedback from industry and internal consultation, it was determined necessary to amend the maximum limit for loss on drying in the minimum quality standard to align with the upcoming European Pharmacopoeia cannabis monograph. This change is to prevent the minimum quality standard from being unnecessarily restrictive in comparison to international standards and the Agency does not consider there is any risk to making this change. Other changes to align with the new monograph would be more restrictive and require further consideration and consultation.

29. Unfortunately, due to the timing of these recent announcements, consideration to further align some aspects of our minimum quality standard with these new internationally accepted specifications could not occur. Addition of international monographs through incorporation by reference would require further external consultation.

30. The Ministry intends to consult on these potential technical changes in 2024 with consideration for whether any further updates to the minimum quality standard will need to be made. Industry has advised that some of the changes in these amendment regulations are important for the sustainability of our medicinal cannabis industry.

31. The Ministry does not recommend delaying bringing the Amendment Regulations into effect to account for any other potential changes to international standards in 2024.

28-day rule waiver

32. The Ministry advises that a waiver of the 28-day rule should be sought for the Amendment Regulations.

33. The Cabinet Manual states that there are some instances where it is appropriate to seek a waiver of the 28-day rule for secondary legislation. This includes where the secondary legislation has little or no effect on the public or confers only benefits to the public.

34. Due to the technical complexity of the Regulations, it has taken time to develop the Amendment Regulations.

35. Industry stakeholders have indicated that without timely regulatory change it will be difficult for a commercially viable industry to be sustained within New Zealand's small medicinal cannabis market. Therefore, immediate adoption of the Amendment Regulations is necessary to best ensure survival of New Zealand's small medicinal cannabis market.

Next steps and proposed timeline

36. It is important that these amendment regulations are brought into effect as soon as possible to ensure that our medicinal cannabis industry can continue to remain sustainable in New Zealand.

37. Following ministerial consultation and any changes to the paper, we recommend lodging the paper with Cabinet Office by 20 June 2024 for the agenda of the Cabinet Legislation Committee meeting scheduled for 27 June 2024.

38. The Ministry intends to inform stakeholders of the proposed changes when agreed to by Cabinet. This will include publication of guidance to assist industry stakeholders in navigating the changes. We also recommend proactively releasing this briefing with the Cabinet paper.

39. A suggested timeline is provided below:

Timeline to bringing the Amendment Regulations into effect:

Step	**Date**
Ministerial consultation	2 weeks (31 May to 14 June 2024)
Lodge Cabinet paper with Cabinet office	By 20 June 2024
Cabinet Legislation Committee meets	27 June 2024
Cabinet meets	1 July 2024
The Ministry announces decision	4 July 2024
Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 come into effect	5 July 2024 (or 2 August 2024 if the 28-day rule is not waived)

Appendix 1: Explanation of each regulation in Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024

Amendment Regulation to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019	**Detail of Amendment/Reasoning**
1 (Title)	N/A
2 (Commencement)	N/A
3 (Principal regulations)	N/A
4 Regulation 4 amended (Interpretations)	Amends definition of 'active ingredient' to clarify what 'any other ingredient' in a cannabis-based ingredient or medicinal cannabis product refers to. Amends the definition of 'cannabis-based ingredient' to include dried cannabis. This enables dosage forms such as dried capsules to be recognised by the regulatory regime. Updates the referenced *European Pharmacopoeia* from version 10.0 to version 11.0 (including supplement 11.3). Amends the definition of 'starting material' to include initial extracts from cannabis so manufacturers can introduce a wider range of cannabis plant formats into their manufacturing process. Introduces definitions for *European Medicines Agency Guideline on Plastic Immediate Packaging Materials*, *British Pharmacopoeia*, and *United States Pharmacopoeia*. Moves the definition for GMP-certified (currently under regulation 9) and introduces the definition for GMP and non-therapeutic purpose for the purposes of the Regulations to add clarity.
5 Regulation 6 amended (Minimum quality standard imposed)	Updates to provide clarity as to when the minimum quality standard applies to ensure that other legitimate activities are not adversely impacted by the Medicinal Cannabis Scheme. These changes: • ensure that minimum quality standard requirements are not applied to starting material that is intended for export • enable medical practitioners to import unverified medicinal cannabis products (if Ministerial approval granted) for a named patient under their care, • ensures that minimum quality standard requirements are not applied to cannabis-based ingredients and medicinal cannabis products if they are imported for non-therapeutic purposes (testing, analysis, or research) • enable cannabis-based ingredients and medicinal cannabis products to be exported without meeting the minimum quality standard, if manufactured to the Good Manufacturing Practice standard and the exporter provides evidence that it is accepted by the importing country.

6 Regulation 7 replaced (Requirements for testing with maximum limits)	Alternative test methods from *United States Pharmacopoeia* and *British Pharmacopoeia* are added in as acceptable test methods. Updated required testing for dried cannabis when used as a cannabis-based ingredient. Added in new regulation that allows manufacturers to reduce duplicate testing when appropriate. This will help manufacturers streamline testing and compliance costs. Updated loss on drying to align with changes internationally.
7 Regulation 8 amended (Other requirements)	Consequential amendment.
8 Regulation 9 replaced (Testing and validation of testing method)	Broadens acceptable laboratory accreditation requirements for testing. Specifies that GMP-certification is required for critical tests, while accepting ISO/IEC 17025:2017 accredited laboratories for other tests. This enables more testing to meet the minimum quality standard to be completed within New Zealand. Add in new provision that exempts requirements in this regulation for testing of container materials.
9 Regulation 11 replaced (Identification of cannabis)	Consequential amendment.
10 Regulation 13 amended (Assay limits for active ingredients)	Provides more flexibility for manufacturers with controlling active ingredients in situations where an ingredient is present at very low levels and difficult to control within a specified range. Enables manufacturers to specify their own assay range for a cannabis-based ingredient, as it does not impact the final product.
11 Regulation 14 amended (No adulteration)	Consequential amendment.
12 Regulation 15 amended (Container material)	Broadens what can be acceptable material for cannabis-based ingredients and medicinal cannabis products to be packaged into. Exempts cannabis-based ingredients from needing to comply with container material requirements if they are not being supplied.
13 Regulation 17 amended (Restrictions on decontamination)	Consequential amendment.
14 Regulation 18 replaced (Pesticides)	Updates regulation 18 which effectively prohibited any pesticides from being used on medicinal cannabis crops. This regulation now: • specifies which pesticide active ingredients may be used on medicinal cannabis crops, including different standards for depending on if the cannabis-based ingredient or medicinal cannabis product is intended to be administered via inhalation

	• provides a mechanism for pesticides that are permitted for use on food to be used on certain medicinal cannabis products • confirms that the use of pesticides must also comply with all other relevant legislative requirements.
15 Regulation 19 amended (Labelling)	Clarifies that medicinal cannabis products that are controlled drugs must have a controlled drug classification statement on the label. This is to align with other medicines that are controlled drugs.
16 Regulation 21 amended (Excipients and other ingredients)	Allows manufacturers to use other excipients in monographs of internationally accepted pharmacopoeias
17 Regulation 22 amended (Types of licensed activity)	Updates the name of nursery activity to seed supply activity
18 Regulation 23 amended (Cultivation activity)	Allows cultivators to export samples of cannabis under their medicinal cannabis licence for the purposes of testing, analysis, or non-therapeutic research. Specifies that possession of cannabis is for the purposes of conducting licensed activities. Allows cultivators to export seeds, cuttings, rootstock, tissue and tissue culture for propagation.
19 Regulation 24 replaced (Nursery activity)	Redefines the scope of this activity to cannabis seed only. This activity previously provided provisions for activities relating to cannabis seed and plants. However, activities involving cannabis plants are more appropriately authorised under a cultivation activity already. The Agency has only ever issued a nursery activity for activities relating to cannabis seed.
20 Regulation 25 amended (Research activity)	Removes provisions of activity that enabled manufacture of cannabis-based ingredients and medicinal cannabis products to better reflect the clinical trial intent of this activity. Specifies that possession of starting material, cannabis-based ingredient or medicinal cannabis product is for the purposes of conducting licensed activities.
21 Regulation 26 amended (Possession for manufacture activity)	Incorporates 'testing' as a purpose for this activity. Updates activity to include the manufacture of initial extracts as starting material. Specifies that possession of starting material, cannabis-based ingredient or medicinal cannabis product is for the purposes of conducting licensed activities.
22 Regulation 27 replaced (Supply activity)	Updates the activity to allow supply of cannabis-based ingredients and medicinal cannabis products that have not been tested to the requirements of the minimum quality standards, by export where the relevant authority of the country has confirmed its willingness to accept the items.

	Updates the activity to allow supply of cannabis-based ingredients and medicinal cannabis products, that have not been tested to the requirements of the minimum quality standard, for the purposes of testing, analysis or non-therapeutic research. Specifies that possession of starting material, cannabis-based ingredient or medicinal cannabis product is for the purposes of conducting licensed activities.
23 Regulation 32 amended (Application for licence)	Broadens the type of documentation that could be submitted for an application. Specifies that the trade name for a cannabis-based ingredient or medicinal cannabis product that meets the minimum quality standard must be unique and distinct from those intended for export only. This will prevent any confusion both domestically and internationally.
24 Regulation 34 amended (Fees for application)	Replace name of nursery activity with seed supply activity.
25 Regulation 35 amended (Other fees: licence for cultivation (or to cultivate prohibited plant))	Consequential amendment.
26 Regulation 36 replaced (Other fees: licence for supply activity)	Clarifies the fee for a product assessment of a dosage product – does not change cost of actual assessment. Consequential amendment of removing references to 'starting material for export'.
27 Regulation 40 amended (Decision to issue licence or to decline licence)	Consequential amendments for: • enabling products to be exported without being verified as meeting the minimum quality standard if they are manufactured to Good Manufacturing Practice and products are accepted by the importing country • enabling the supply of ingredients and products without being verified as meeting the minimum quality standard for non-therapeutic purposes.
28 Regulation 43 amended (Issue and form of licence)	Consequential amendments.
29 Regulation 47 amended (Certain changes not to be made without approval from Director-General)	Removing reference to 'starting material for export'.
30 Regulation 54 replaced (Cannabis, ingredients and products to be dealt with responsibly)	Adding in reference to starting material.

31 Regulation 56 replaced (Security of cannabis, ingredients and products)	Adding in reference to starting material.
32 Regulation 57 amended (Police and Director-General to be notified of unauthorised removal, loss, or activity)	Adding in reference to starting material.
33 Regulation 58 amended (Locations must be available for inspection)	Adding in reference to starting material.
34 Regulation 59 amended (Samples taken for testing)	Adding in reference to starting material.
35 Regulation 60 replaced (Destruction of cannabis, ingredients and products)	Adding in reference to starting material.
36 Regulation 62 amended (Records for cultivation activity)	Technical clarification on who a "holder of a licence" refers to.
37 Regulation 63 replaced (Records for nursery activity)	Clarifies that amounts of cannabis destroyed or disposed of needs to be recorded.
38 Regulation 64 amended (Records for research activity)	Clarifies that amounts of cannabis destroyed or disposed of needs to be recorded.
39 Regulation 65 amended (Records for possession for manufacture activity)	Clarifies that amounts of cannabis destroyed or disposed of needs to be recorded.
40 Regulation 66 amended (Records for supply activity)	Clarifies that amounts of cannabis destroyed or disposed of needs to be recorded.
41 Regulation 67 amended (Records of stocktake for any activity)	Clarifies that "end of any year" refers to 31 December of any year which aligns with stocktake requirements in the Misuse of Drugs Regulations 1977 Includes a reporting requirement for the stocktake report to align with Misuse of Drugs Regulations 1977
42 Regulation 79 amended (Offence to supply to unauthorised persons)	Adding in reference to starting material.
43 Schedule 1 amended	Provides transitional arrangements for licences and activities affected by the Amendment Regulations. This will ensure that licence holders are able to

	continue with their activities without requiring new licences following the Amendment Regulations coming into effect.
Amendment Regulation to the Misuse of Drugs Regulations 1977	**Detail of Amendment/Reasoning**
44 (Principal regulations)	N/A
45 Regulation 3B amended (Application to industrial hemp)	Enables a licence to possess controlled drugs (issued under the Misuse of Drugs Regulations 1977) to be issued for industrial hemp to facilitate New Zealand researchers using industrial hemp for non-therapeutic research.
46 Regulation 3C amended (Application to medicinal cannabis products)	Enables a licence to possess controlled drugs (issued under the Misuse of Drugs Regulations 1977) to be issued for medicinal cannabis to facilitate New Zealand researchers using medicinal cannabis for non-therapeutic research.
47 Regulation 28 amended (Custody of controlled drugs)	Exempts a medicinal cannabis licence holder who has been proven to have adequate security for the activities of their licence from having to comply with the custody of controlled drugs requirements under the Misuse of Drugs Regulations 1977. This is to prevent duplicate security requirements and to address the non-applicability of approved safes to cannabis.
Amendment Regulation to the Medicines Regulations 1984	**Detail of Amendment/Reasoning**
48 (Principal regulations)	N/A
49 Regulation 4A amended (Standard for CBD products)	Clarifies applicability of the minimum quality standard to CBD products so other legitimate activities are not adversely impacted.
50 Regulation 38A inserted (Prohibition relating to personal importation of CBD products)	New regulation to specify that personal importation of CBD products by overseas courier or mail is prohibited. This is already current practice but is regulated indirectly through application of the minimum quality standard to imported products.
51 Regulation 45B amended (Licences that relate to CBD products)	Clarifies where a licence may be issued authorising its application to the supply of CBD products so other legitimate licensed activities are not adversely impacted.
52 Regulation 64 amended (Offences)	Consequential amendment.

Briefing

Update on changes proposed to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019

Date due to MO:	19 March 2024	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	H2024037065
To:	Hon Dr Shane Reti, Minister of Health Hon David Seymour, Associate Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
Simon Medcalf	Deputy Director-General, Regulation and Monitoring	s 9(2)(a)
Chris James	Group Manager, Medsafe, Regulation and Monitoring	s 9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Update on changes proposed to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019

Security level:	IN CONFIDENCE	**Date:**	18 March 2023
To:	Hon Dr Shane Reti, Minister of Health Hon David Seymour, Associate Minister of Health		

Purpose of report

1. This briefing provides you with background information on the Medicinal Cannabis Scheme (the Scheme), the changes proposed to the Scheme, and the progress of those changes.

Summary

2. The Medicinal Cannabis Scheme (the Scheme) came into effect on 1 April 2020, when the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Regulations) came into force. The aim of the Scheme is to improve patient access to quality medicinal cannabis products.

3. Since the Scheme's inception, the Medicinal Cannabis Agency (the Agency) has granted licences to 59 applicants and verified 41 medicinal cannabis products as meeting the minimum quality standard. The licences granted covered a range of activities, including cultivation, nursery, possession for manufacture, and supply.

4. Since the Scheme has been in operation, some amendments have been identified that would improve the sustainability of medicinal cannabis industry in New Zealand.

5. Feedback from industry indicates that timely regulatory change is necessary for a commercially viable industry to be sustained within New Zealand's small medicinal cannabis market.

6. On 24 July 2023, Cabinet (under the previous Government) agreed to changes being made to the Scheme to better support the economic and research opportunities of the New Zealand medicinal cannabis industry.

7. Drafting of the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (the Amendment Regulations) is well advanced, with a limited exposure draft ready to be provided to a small number of industry experts.

8. Following departmental consultation, a draft Cabinet Legislation Committee paper alongside the Amendment Regulations will be provided to you. With your approval, this paper will be lodged with Cabinet.

Recommendations

We recommend you:

a) **Note** that regulatory change is needed to address technical issues and better support export and research activities in the Medicinal Cannabis Scheme

b) **Note** that Cabinet agreed to changes being made to improve the Medicinal Cannabis Scheme to address unintended barriers with the Regulations

c) **Agree** to drafting of the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 continuing, and for the Ministry to undertake departmental consultation and targeted engagement with a small number of industry representatives. **Yes/No**

d) **Note** that, if agreed to, following departmental consultation, the Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 will be sent to you for approval before lodging with Cabinet.

Simon Medcalf
Deputy-Director General
Regulation and Monitoring
Date: 18 March 2024

Hon Dr Shane Reti
Minister of Health
Date: 27/3/2024

Hon David Seymour
Associate Minister of Health
Date: 1/4/24

Update on changes proposed to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019

Background

1. The Medicinal Cannabis Scheme (the Scheme) was introduced with the aim of improving access to quality medicinal cannabis products for New Zealand patients.

2. The Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Regulations) commenced on 1 April 2020 and gave effect to the Scheme. The Regulations detail requirements for:

   a. minimum quality standards for starting material (raw cannabis plant material), cannabis-based ingredients (generally purified or raw cannabis extracts intended for use in a dosage product), and medicinal cannabis products

   b. a licensing regime for medicinal cannabis cultivation, nursery, manufacturing, supply and (clinical) research activities.

3. The Medicinal Cannabis Agency (the Agency), which sits within Medsafe and is a business unit of the Ministry of Health, administers the Scheme and ensures that medicinal cannabis products meet the minimum quality standard. The Agency's costs are recovered primarily through licence and product application fees.

4. Since the Scheme's introduction, the Agency has granted 59 applicants with licences covering a range of activities, including cultivation, nursery, possession for manufacture, and supply. The Agency has also verified 41 medicinal cannabis products as meeting the minimum quality standard. These include both CBD products and THC containing products, in a range of formulations, including oral solutions and sublingual drops, and dried flower preparations verified either for inhalation or for preparation as a tea.

5. With respect of quantity supplied within New Zealand, the Agency has been advised that 16,346 packs were supplied in November 2023, and 15,587 packs were supplied in December 2023. This includes products verified under the Scheme (as well as unverified CBD products imported directly into New Zealand, although this is likely a very small proportion of the total supplied).

6. Since the Scheme was introduced, some unintended barriers created by the Regulations have been identified. These are, in part, due to evolving business models within the sector. Furthermore, technical changes are considered necessary to improve the workability of the minimum quality standard (such as updating testing requirements) and the operation of the licensing framework.

Regulatory barriers

7. The Scheme was put in place to increase access to quality medicinal cannabis products for New Zealand patients, however, it has become apparent that New Zealand's small population and relatively small medicinal cannabis market is insufficient to support a domestic industry.

8. Feedback from the industry indicated that the current export settings are creating problems for potential exporters and local manufacturers due to various factors, including:

   a. high costs of complying with the New Zealand standard when only considering export to a country with a different standard

   b. challenges with the timing of obtaining New Zealand verification prior to the export of products with a limited shelf life

   c. preventing local cultivators from exporting seed to explore export opportunities.

9. Some industry stakeholders have indicated that a significant export market is required for the local medicinal cannabis industry to be sustainable. A lack of ability to easily export may lead to some businesses closing.

10. Proposals were developed based on the consultation with industry stakeholders and the experiences of the Agency. The proposals consisted mostly of technical amendments with some policy decisions to improve the Scheme by:

    a. changing the export settings for starting material, cannabis-based ingredients, medicinal cannabis products and cannabis seed to better support export opportunities

    b. broadening the medicinal cannabis categories (and amending the associated quality standard to better reflect new risks)

    c. adding a licence pathway for non-therapeutic research where the cannabis plant material can be sourced from the Scheme or the industrial hemp framework.

11. These proposals are aimed at improving the operation of the Scheme, and better supporting the economic and research objectives of industry stakeholders without compromising on final product quality and safety. Feedback from industry largely supported the proposed changes.

12. Where concerns were raised by industry, these were in three main areas.

    a. Timing of the changes occurring before adoption of the new Cannabis Monograph in the European Pharmacopoeia.

    b. Removal of the minimum quality standard for export could have a reputational risk if medicinal cannabis from New Zealand is of a poor quality.

    c. A desire to further reduce the testing burden of the minimum quality standard.

13. These concerns were considered and mitigating factors were included where appropriate in drafting the changes to the Regulations.

Policy decisions

14. On 24 July 2023, Cabinet (under the previous Government) agreed to regulatory and technical changes being made to the Medicinal Cannabis Scheme to better support the economic and research opportunities of the sector [CAB-23-MIN-0313].

15. The key policy decisions included agreement to:

    a. amend the definitions of 'starting material' and 'cannabis-based ingredient' to capture a wider range of cannabis plant forms

    b. enable export of cannabis seed

    c. remove the requirement to meet the minimum quality standard for exports of starting material

    d. remove the requirement for exports of cannabis-based ingredients and medicinal cannabis products to be verified as meeting the minimum quality standard prior to export if manufactured under Good Manufacturing Practice and they are accepted by the importing country

    e. allow a licence to possess controlled drugs (issued under the Misuse of Drugs Regulations 1977) to be issued to authorise non-therapeutic research activities using starting material, cannabis-based ingredients and medicinal cannabis product

    f. allow medicinal cannabis licence holders to supply starting material, cannabis-based ingredients, and medicinal cannabis products for non-therapeutic research activities

    g. re-define the scope of nursery activity as seed supply

    h. make technical changes to improve and clarify the minimum quality standard requirements

    i. make technical changes to licensing requirements to help provide clarification, improve operations of the licensing framework, and to align with existing requirements in the Misuse of Drugs Regulations 1977.

16. The Misuse of Drugs (Medicinal Cannabis) Amendment Regulations 2024 (the Amendment Regulations) would bring these policy decisions into effect.

17. The Amendment Regulations would reduce regulatory barriers and support potential economic opportunities with medicinal cannabis, including those from export markets. It also is envisaged that a successful domestic industry will increase the availability and supply of medicinal cannabis products in New Zealand. This will likely improve the affordability and increase access for patients in the long term.

Intended process for proposed changes

18. Drafting of the Amendment Regulations is well advanced and anticipated to be ready for consideration by Cabinet shortly.

19. The Ministry intends to send this paper alongside the latest draft of the Amendment Regulations out for Departmental Consultation with the following departments: the Ministry of Foreign Affairs and Trade, Te Whatu Ora, the Department of the Prime Minister and Cabinet, the Ministry of Business, Innovation and Employment, the National Drug Intelligence Bureau, New Zealand Police, New Zealand Customs, the Ministry for Primary Industries, Treasury (Regulatory Strategy), Pharmac, the Ministry of Justice, Department of Corrections, New Zealand Trade and Enterprise, and Whaikaha.

20. A limited exposure draft of the Amendment Regulations is intended, subsequent to approval from the Ministry's Chief Legal Advisor in accordance with Cabinet Office Circular CO(19)2: Attorney-General's Protocol for release of Draft Government Legislation outside of the Crown, to be shared with a small number of industry experts. These experts have been selected through consultation with the New Zealand Medicinal Cannabis Council and the Agency to ensure that the feedback is constructive and representative of the industry. Feedback from this limited exposure draft will be considered before finalising the draft of the Amendment Regulations.

Next steps

21. It is important to make timely progress on the Amendment Regulations to ensure that our medicinal cannabis industry can continue to remain sustainable in New Zealand.

22. The limited exposure draft and draft Cabinet paper have been prepared and are ready for release upon your decision. It is intended they go out for consultation for one week.

23. Subsequent to review of any feedback, the Ministry will then provide you with a draft Cabinet Legislation Committee paper seeking approval to submit the Amendment Regulations to the Executive Council.

ENDS.

Minister's Notes