Minister of Health

Cabinet material, associated briefing and regulatory impact statement: Improving the Medicinal Cannabis Scheme to better support economic and research opportunities

4 September 2023

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

Title of Cabinet paper:

- Medicinal Cannabis: Improving the Medicinal Cannabis Scheme to better support economic and research opportunities (including Regulatory Impact Statement: Regulatory amendments to improve the economic opportunities of the Medicinal Cannabis Scheme)

Title of Ministerial briefing:

- Draft Cabinet paper: Improving the Medicinal Cannabis Scheme to better support economic and research opportunities (H2023025508)

Titles of minutes:

- Report of the Cabinet Social Wellbeing Committee: Period Ended 21 July 2023 (CAB-23-MIN-0313)
- Improving the Medicinal Cannabis Scheme to Better Support Economic and Research Opportunities (SWC-23-MIN-0089)

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 codes:

s9(2)(a): to the privacy of individuals

Out of scope of the subject of this proactive release.

CAB-23-MIN-0313

Cabinet

Minute of Decision

Report of the Cabinet Social Wellbeing Committee: Period Ended 21 July 2023

On 24 July 2023, Cabinet made the following decisions on the work of the Cabinet Social Wellbeing Committee for the period ended 21 July 2023:

[redacted]	Out of scope	[redacted]
[redacted]	[redacted]	[redacted]
SWC-23-MIN-0089	**Improving the Medicinal Cannabis Scheme to Better Support Economic and Research Opportunities** Portfolio: Health	CONFIRMED
[redacted]	Out of scope	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Rachel Hayward
Secretary of the Cabinet

SWC-23-MIN-0089

Cabinet Social Wellbeing Committee

Minute of Decision

Improving the Medicinal Cannabis Scheme to Better Support Economic and Research Opportunities

Portfolio **Health**

On 19 July 2023, the Cabinet Social Wellbeing Committee:

Background

1 **noted** that the Medicinal Cannabis Scheme was introduced to improve access to quality medicinal cannabis products;

2 **noted** that there is an opportunity to improve the Medicinal Cannabis Scheme for industry stakeholders so that research and export opportunities can be better supported;

3 **noted** that industry stakeholders have indicated that without regulatory change, it is unlikely that the medicinal cannabis industry will be sustainable in New Zealand's small market;

Medicinal cannabis categories

4 **agreed** to amend the definitions of 'cannabis-based ingredient' and 'starting material' to allow for a broader range of cannabis plant forms;

5 **agreed** to the minimum quality standard for 'cannabis-based ingredient' being amended to address any new risks to product quality for when dried cannabis is used as an ingredient;

The minimum quality standard

6 **agreed** that technical changes will be made to improve and update the minimum quality standard requirements;

7 **agreed** to clarify that the minimum quality standard only applies to cannabidiol products intended for human therapeutic use where the active ingredients are derived from cannabis plant;

8 **agreed** to clarify that the minimum quality standard does not apply to starting material, cannabis-based ingredients or medicinal cannabis products that are not intended for therapeutic end use;

Export of medicinal cannabis

9 **agreed** to allow cannabis seed to be exported as an activity under a medicinal cannabis licence with a cultivation or nursery (seed supply) activity;

10 **agreed** to allow a medicinal cannabis licence holder with a cultivation activity to export samples of starting material without the requirement to meet the minimum quality standard for the purposes of testing, analysis or research;

11 **agreed** to allow a medicinal cannabis licence holder with a supply activity to export starting material, cannabis-based ingredients and medicinal cannabis products for the purposes of testing, analysis, manufacturing or research;

12 **agreed** to remove the minimum quality standard requirement for exports of starting material;

13 **agreed** to allow cannabis-based ingredients and medicinal cannabis products to be exported without meeting the minimum quality standard, provided they are manufactured to Good Manufacturing Practice and the exporter holds evidence that the products are accepted by the importing country;

General licensing requirements

14 **agreed** to technical changes being made to the 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;

Nursery activity

15 **agreed** to amend the nursery activity to allow for the procurement and supply of cannabis seed only, and to rename this activity as ‘seed supply’;

16 **agreed** to allow a nursery activity on a medicinal cannabis licence to remain in effect until the specified expiry date despite the activity being renamed;

Fees

17 **agreed** to correct the dosage product assessment fee to $6,700 excluding GST to reflect assessment of the final dosage product only;

Scientific research with cannabis

18 **agreed** to allow imports of cannabis-based ingredients or medicinal cannabis products without the requirement to meet the minimum quality standard for the purposes of testing or research;

19 **agreed** to allow a licence to possess controlled drugs to be issued for non- therapeutic research activities using starting material, cannabis-based ingredients, medicinal cannabis products and industrial hemp framework provided all other licencing requirements are met;

20 **agreed** to allow medicinal cannabis licence holders to supply starting material, cannabis-based ingredients, and medicinal cannabis products for non- therapeutic research activities with the appropriate authorisation;

Approval for drafting instructions

21 **invited** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to the above decisions;

22 **authorised** the Ministry of Health to consult with a small number of industry experts on a limited exposure draft of the amendments, subject to approval from the Attorney-General.

Rachel Clarke
Committee Secretary

Present:
Hon Kelvin Davis
Hon Grant Robertson
Hon Dr Megan Woods
Hon Jan Tinetti (Chair)
Hon Willie Jackson
Hon Peeni Henare
Hon Kieran McAnulty
Hon Ginny Andersen
Hon Barbara Edmonds
Hon Jo Luxton

Officials present from:
Office of the Prime Minister
Officials Committee for SWC

Briefing

Draft Cabinet paper: Improving the Medicinal Cannabis Scheme to better support economic and research opportunities

Date due to MO:	29 May 2023	**Action required by:**	23 June 2023
Security level:	IN CONFIDENCE	**Health Report number:**	H2023025508
To:	Hon Dr Ayesha Verrall, Minister of Health		
Consulted:	Health New Zealand: ☒ Māori Health Authority: ☒		

Contact for telephone discussion

Name	Position	Telephone
Clare Perry	Deputy Director-General, Regulatory Services	s 9(2)(a)
Chris James	Group Manager, Medsafe	s 9(2)(a)

Minister's office to complete:

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

Comment:

Draft Cabinet paper: Improving the Medicinal Cannabis Scheme to better support economic and research opportunities

Security level:	IN CONFIDENCE	**Date:**	29 May 2023
To:	Hon Dr Ayesha Verrall, Minister of Health		

Purpose of report

1. This report attaches a draft Cabinet paper and a Regulatory Impact Statement with regulatory proposals to improve the Medicinal Cannabis Scheme.

2. This report discloses all relevant information and implications.

Summary

3. The Medicinal Cannabis Scheme (the Scheme) aims to improve patient access to quality medicinal cannabis products.

4. The Scheme (administered by the Medicinal Cannabis Agency (the Agency)) has been in effect since 1 April 2020 and has made several domestically produced and imported medicinal cannabis products, that meet the minimum quality standard, available for New Zealand patients.

5. Since the Scheme was introduced, some unintended barriers with the regulations have been found due to evolving business models within the sector. Furthermore, technical changes are required to improve the workability of the minimum quality standard (such as updating testing requirements) and the operation of the licensing framework.

6. These regulatory proposals were developed based on consultation with industry stakeholders and the experiences of the Agency. The proposals consist of mostly technical amendments with some policy decisions to better support the economic and research objectives of the Scheme by:

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

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

   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.

7. The key focus of these proposals is ensuring the regulatory settings are appropriately balanced to better support our domestic medicinal cannabis market without compromising on product quality or safety for New Zealand patients.

8. Manatū Hauora has consulted with the following departments on these proposals: Te Whatu Ora, Whaikaha, Te Aka Whai Ora, Ministry of Justice, Ministry of Business,

Innovation and Employment, Ministry of Foreign Affairs and Trade, New Zealand Police, Pharmac, Ministry for Primary Industries, New Zealand Customs Service, Department of Corrections, and the Department of Prime Minister and Cabinet.

9. There is urgency to prioritising and implementing these changes, especially regarding export settings. Industry stakeholders have indicated that local companies may withdraw from the market soon unless they can access opportunities from export markets more readily. An unsuccessful domestic industry would be counterproductive to the Government's commitment to improve access to quality medicinal cannabis products.

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 without timely change, there is a significant risk that local companies will struggle to remain sustainable in New Zealand's small medicinal cannabis market which would have a negative impact on patient access to medicinal cannabis products

c) **Agree** to circulate the draft Cabinet paper to your colleagues for consultation **Yes/No**

d) **Agree** to lodge the attached Cabinet paper, with any changes, by 12 July 2023 **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 Regulatory Impact Statement on the Ministry's website at the time of the announcement. **Yes/No**

Dr Diana Sarfati
Director-General of Health
Te Tumu Whakarae mō te Hauora

Date: 22/6/23

Hon Dr Ayesha Verrall
Minister of Health

Date: 24/6/23

Draft Cabinet paper: Improving the Medicinal Cannabis Scheme to better support economic and research objectives

Background

10. The Medicinal Cannabis Scheme was introduced to improve access to quality medicinal cannabis products for New Zealand patients.

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

    a. minimum quality standards for starting material (raw cannabis plant material) for export, cannabis-based ingredients (active ingredient), and medicinal cannabis products

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

12. In May 2022, we briefed the then Minister of Health on problems with the current export settings for medicinal cannabis and the then Minister agreed to consult with the medical cannabis sector on regulatory change [HR 20220559].

Targeted engagement with industry stakeholders

13. In December 2022, the 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.

14. These proposals are aimed at improving the operations of the Scheme, compliance requirements, 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 that are detailed in the Cabinet paper.

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

Proposed regulatory changes

Medicinal cannabis categories

16. Under the Scheme, medicinal cannabis can be regulated in 3 ways depending on the stage of manufacturing:

    a. starting material (raw cannabis plant material)

    b. cannabis-based ingredient (active pharmaceutical ingredient used in a product)

    c. medicinal cannabis product (finished product intended for patient use).

17. A change to encompass a broader range of plant forms to be used as starting material and as cannabis-based ingredients, will better reflect the different types of material that can be used at the different stages of the manufacturing process. It will also mean that Good Manufacturing Practice (GMP) requirements are applied at appropriate stages

which is consistent with the GMP framework. GMP ensures good controls are in place during manufacturing and is considered regulatory best practice for medicines.

18. These changes can improve innovation and productivity in the sector, and ensure our regulatory framework recognises a wider range of medicinal cannabis dosage forms.

Export settings for medicinal cannabis

19. In the design of the Scheme, it was always anticipated that the New Zealand medicinal cannabis industry would need to look for export markets to be sustainable. New Zealand's small population and relatively small medicinal cannabis market are insufficient to support a domestic industry.

20. The current export settings are creating problems for potential exporters and local manufacturers.

21. Feedback from industry indicates that the minimum quality standard for exports of medicinal cannabis is a barrier to economic opportunities in overseas markets. Some stakeholders have indicated that changing export settings is critical to the survival of our local industry.

22. The draft Cabinet paper proposes changes to export settings to better support the economic opportunities for our domestic medicinal cannabis industry.

23. Manatū Hauora intends to address any potential risks from lower quality products reaching international markets by only permitting exports:

    a. of ingredients and products manufactured under appropriate controls (ie, Good Manufacturing Practice) and

    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) and

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

Better supporting research with cannabis in New Zealand

24. When the Scheme was introduced, regulations were introduced to provide distinction between the different regulatory frameworks overseeing cannabis activities in New Zealand (Misuse of Drugs Regulations 1977 and the Medicinal Cannabis Scheme). For example, this means that cannabis grown under the Scheme for a therapeutic purpose is subject to the necessary controls for a medicine and cannot be supplied for any other use.

25. Therefore, a licence to possess controlled drugs (a licence which authorises research activities issued under the Misuse of Drugs Regulations 1977) cannot be issued for any starting material, cannabis-based ingredient or medicinal cannabis product that has been grown or produced under the Medicinal Cannabis Scheme.

26. A similar provision exists for industrial hemp which ensures all activities relating to industrial hemp are conducted solely under the Industrial Hemp framework.

27. Unfortunately, this has meant that local researchers cannot access domestically grown cannabis material (grown under the medicinal cannabis or industrial hemp framework) for other legitimate scientific purposes.

28. Although researchers could potentially import cannabis or set up facilities to grow their own crops, this is significantly more expensive and could be prohibitive, compared to obtaining cannabis material already being grown and manufactured domestically.

29. The Agency and Medsafe have received requests from stakeholders wanting to conduct research activities with cannabis that are not currently captured by the provisions of the Medicinal Cannabis Regulations (which enable clinical trials and therapeutic product development only). Examples of these activities include analytical testing, quantitative and qualitative analysis (eg, toxicology, forensic or scientific research) and microbial testing.

30. Permitting researchers to use cannabis grown under the Medicinal Cannabis Scheme or Industrial Hemp framework for scientific research will better support innovation and reduce barriers to research in New Zealand.

31. The proposed changes will enable an existing framework (licence to possess controlled drugs) under the Misuse of Drugs Regulations 1977 to authorise non-therapeutic research activities involving medicinal cannabis and industrial hemp.

32. This, along with allowing imports of medicinal cannabis that do not meet the minimum quality standard for research purposes, will ensure there is a pathway in the regulations regarding research licences and activities for commercial aspects of the medicinal cannabis industry.

33. The Misuse of Drugs Act 1975 permits research activities with cannabis if authorised via a licence under the Act. The amendments to the Misuse of Drugs Act in 2019 did not consider cannabis research. This regulatory change addresses an unintended impact on cannabis related research and development when regulation 3B and 3C were introduced into the Misuse of Drugs Regulations. Regulation 3B prevents a licence to possess controlled drugs from being issued for industrial hemp. Regulation 3C prevents a licence to possess controlled drugs from being issued for medicinal cannabis.

Technical changes

Changes required to update and improve the workability of the minimum quality standard

34. The draft Cabinet paper highlights technical changes are required to improve the minimum quality standard.

35. The proposed technical changes are outlined in the table below.

Proposed change	Reasoning
Update the monographs incorporated by reference in the minimum quality standard	The 10.0 edition of the *European Pharmacopoeia* referenced in the Medicinal Cannabis Regulations has been superseded
Add new monographs for different tests that can be used to assess the quality	Reflect new scientific developments in this area. Enables some monographs from the

specification of medicinal cannabis including test methods and limits	*British* and *United States Pharmacopoeia* to be accepted
Add new monographs for accepted excipients (ingredients that are not the active ingredient) and widening the range of permitted packaging materials	Better aligns with requirements expected for other medicines and allows manufacturers to use a broader range of packaging materials
Exempt the container material requirement for cannabis-based ingredients that are being used at the same site	In some situations, cannabis-based ingredients are not being sold or distributed. It is reasonable for container material requirements to not apply
Remove requirement for excipient and container material testing to be at a GMP certified site	Better aligns with requirements expected for other medicines
Reduce areas where duplicative testing occurs	The current regulations require most 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
Amend testing limit requirements for active ingredients	Better reflect what can be reasonably controlled in the manufacturing process
Clarifying definition of 'active ingredient'	Address confusion that has been raised by industry stakeholders
Clarifying definition of 'starting material' and 'medicinal cannabis product' to provide greater distinction	Address confusion that has been raised by industry stakeholders
Clarifying applicability of minimum quality standard: • The standard does not apply to cannabidiol (CBD) products carried by travellers when they enter or leave New Zealand • The standard does not apply to CBD products supplied for a clinical trial • The standard does not apply to CBD products when used for veterinary medicines, for non-therapeutic uses and when the ingredients are not derived from a cannabis plant	Address some confusion that has been raised by stakeholders Aligns the regulation of CBD products with regulation on other medicines carried by travellers and used in clinical trials, as per the Medicines Act 1981 Provides clarification that the minimum quality standard was developed to address risks associated with the production of a cannabis-derived product specifically. It is not appropriate to use the minimum quality standard to assess the risks associated with veterinary use, non-therapeutic uses and manufacturing of a product that is not derived from cannabis

Broadening the range of accepted laboratory accreditation requirements for some tests and method validation. Tests that impact on dose accuracy must continue to be completed at a GMP site	Better reflects the laboratory testing capabilities in New Zealand to support local products entering the domestic market
Amend labelling requirements for medicinal cannabis products to include a controlled drug classification statement	Aligns with the labelling requirements for other controlled drugs under the Misuse of Drugs Regulations 1977
Allow medical practitioners to import medicinal cannabis products (controlled drugs) that do not meet the minimum quality standard for a named patient	The Medicinal Cannabis Regulations limit the importation of these products to be undertaken by pharmacists only and has omitted medical practitioners. Enabling medical practitioners to import these medicinal cannabis products, aligns with section 25 of the Medicines Act 1981 which allows medical practitioners to directly import unapproved medicines for a named patient. This does not change the requirement for prescribers to obtain Ministerial approval for prescribing a medicinal cannabis product that has not been verified as meeting the minimum quality standard.
Update requirements for pesticide use on cannabis crops	Alternative requirements to manage pesticide use is required to allow this regulation to function as intended

36. Subject to Cabinet agreement, Manatū Hauora will make any new material that will be incorporated by reference into the Medicinal Cannabis Regulations available for public viewing for a consultation period. This will fulfil obligations for incorporation by reference under the Legislation Act 2019.

Review of pesticides permitted to be used on cannabis crops

37. The current regulation managing pesticides permitted to be used on cannabis crops is unworkable and effectively prohibits use of any pesticides on these crops. Although feedback from the 2019 consultation indicated that local industry would only be interested in growing organic cannabis, current feedback suggests that industry would like to use pest control products. Alternative requirements to manage pesticide use are required to allow this regulation to function as intended.

38. Manatū Hauora has limited expertise in assessment of pesticide use. To address this, the Agency convened a working group consisting of members from Environmental Protection Authority, Ministry for Primary Industries, Plant and Food Research, Institute of Environmental Science and Research, and industry representatives, to develop new requirements that would adequately balance the need to permit pesticide use while limiting impact of potential residue on patient safety.

Changes required to clarify and improve the operation of the licensing framework

39. The table below outlines the technical changes required to the licensing framework under the Scheme so it can function as intended.

Proposed change	Reasoning
Clarify that possession of cannabis is only permitted for performing the functions of licensed activities	Better clarifies the intent of this regulation
Remove "producing or manufacturing a cannabis-based ingredient or medicinal cannabis product" as a permitted activity from the research activity under a medicinal cannabis licence	Helps better reflect the intent of research activity – for the purpose of clinical trials. This function is already enabled under a possession for manufacture activity, which is the more appropriate authorisation
Allow 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
Allow a broader range of documentation that applicants can supply to support their licence application	The current regulation specifies that applicants must supply standard operating procedures. Sometimes, applicants have the required information in other forms of documentation which would be acceptable
Clarify that the dosage product assessment fee is $6,700 excluding GST	Better reflects cost of assessment
Clarify record keeping requirements for cultivators and medicinal cannabis licence holders	Better clarifies intent of this regulation, including requirements that destroyed material also needs to be recorded
Amend stocktake reporting dates to align with the Misuse of Drugs Regulations 1977	Ensures consistency between legislation
Include new regulation to reference controlled drug storage requirements and regulation on advertising of controlled drugs under the Misuse of Drugs Regulations 1977	These requirements also apply to medicinal cannabis licence holders. This will clarify the application of these requirements to medicinal cannabis licence holders
Amend requirements for licences that relate to CBD products	The current regulation 45B of the Medicines Regulations 1984 is unintentionally creating operational difficulties for licence holders and the regulator. An update is needed to ensure that the regulation is operationally sound and functioning as intended. For example, the regulation requires a licence holder to only manufacture a CBD product that has been verified as meeting

	the minimum quality standard. This is inconsistent with the normal manufacturing process, as a licence holder needs to be authorised to manufacture a CBD product first before it can be submitted to the Agency for verification.

Consultation

40. Manatū Hauora consulted with medicinal cannabis industry stakeholders and the New Zealand Medicinal Cannabis Council in the development of significant proposals. Feedback largely supported these proposals. Consultation analysis on export settings for starting material, cannabis-based ingredients and medicinal cannabis products is covered in the Regulatory Impact Statement.

41. These proposals have been consulted on with the following departments: Te Whatu Ora, Whaikaha, Te Aka Whai Ora, Ministry of Justice, Ministry of Business, Innovation and Employment, Ministry of Foreign Affairs and Trade, New Zealand Police, Pharmac, Ministry for Primary Industries, New Zealand Customs Service, Department of Corrections, and Department of Prime Minister and Cabinet.

Next Steps

42. Following ministerial consultation and any changes to the paper, we recommend lodging the paper with Cabinet Office by 12 July 2023 for the agenda of the Cabinet Social Wellbeing Committee meeting scheduled for 19 July 2023.

43. Manatū Hauora intends to inform stakeholders of the proposed changes when agreed to by Cabinet. We also recommend proactively releasing this report with the Cabinet paper and Regulatory Impact Statement.

44. It will be important to make timely progress on these proposals to ensure that our medicinal cannabis industry can continue to remain sustainable in New Zealand. A suggested timeline is provided below.

45. Timeline for regulatory change to Medicinal Cannabis Scheme

Step	Date
Ministerial consultation	2 weeks (12 to 20 June 2023)
Lodge Cabinet paper with Cabinet office	12 July 2023
Cabinet Social Wellbeing Committee meets	19 July 2023
Cabinet meets	24 July 2023
Manatū Hauora announces policy decisions	27 July 2023
If Cabinet has agreed, Manatū Hauora will make any new materials/monographs to be incorporated by reference available for public consultation to meet requirements under the Legislation Act 2019 (see paragraph 31)	August 2023

Drafting instructions are sent to Parliamentary Counsel Office (PCO) and drafting of regulations begins	August to October 2023
Draft Cabinet Legislation Committee paper is sent to Minister attaching amendment regulations	November 2023
Ministerial consultation	November 2023
Cabinet Legislation Committee meets	November 2023
Cabinet meets, Executive Council approves amendment regulations	November 2023
Amendment regulations take effect	December 2023

ENDS.

Minister's Notes

In confidence

Office of the Minister of Health

Chair, Cabinet Social Wellbeing Committee

Medicinal Cannabis: Improving the Medicinal Cannabis Scheme to better support economic and research opportunities

Proposal

1 This paper seeks agreement to proposals that improve the Medicinal Cannabis Scheme. The changes require amendments to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Medicinal Cannabis Regulations), Misuse of Drugs Regulations 1977, and Medicines Regulations 1984.

Relation to government priorities

2 The proposals in this paper are necessary to achieve the Government's commitment to improving access to quality medicinal cannabis products.

Executive Summary

3 The Medicinal Cannabis Scheme (the Scheme) has been in effect since 1 April 2020. It aims to improve access to affordable, quality products for New Zealand patients.

4 Since the Scheme was introduced, some unintended barriers with the regulations have been found due to evolving business models in the medicinal cannabis sector. Feedback from consultation with the industry has indicated that timely regulatory change is necessary so a commercially viable industry can be sustained within New Zealand's small medicinal cannabis market. Without regulatory change, it is likely that the number of different products available (especially those locally produced) will be reduced, and available products could become more expensive.

5 I therefore propose that the following regulatory changes are made to the Scheme to better support the economic and research opportunities for industry:

5.1 broadening the medicinal cannabis category definitions

5.2 changing the requirements for exports of medicinal cannabis so New Zealand companies can access export markets more readily

5.3 allowing a licence to possess controlled drugs (under the Misuse of Drugs Regulations 1977) to authorise non-therapeutic research with cannabis plant material sourced from the Scheme or the industrial hemp framework.

6 In addition, I am proposing some minor technical changes are made to improve the operation of the licensing framework and clarify requirements of the minimum quality standard. This will help the Scheme function as intended without compromising the quality and safety of products made available to New Zealand patients.

7 The proposed regulatory and technical changes aim to better support the sustainability of the medicinal cannabis industry. This could potentially bring increased trade and economic benefits to New Zealand and ultimately improve access to more affordable products that meet appropriate quality standards.

Background

8 Cabinet agreed on 17 December 2018 [CAB-18-MIN-0641] that the Medicinal Cannabis Scheme (the Scheme) would include a licensing regime for the cultivation of cannabis for medicinal use, and the manufacture and supply of medicinal cannabis products. The Scheme was established to increase access to quality medicinal cannabis products by enabling the cultivation and the manufacture of medicinal cannabis products in New Zealand, and the import of products from overseas.

9 The Medicinal Cannabis Regulations commenced on 1 April 2020. The Medicinal Cannabis Regulations established the Medicinal Cannabis Agency (the Agency) and detailed requirements for:

9.1 a minimum quality standard for starting material (raw cannabis plant material) for export, cannabis-based ingredients (active ingredient) and medicinal cannabis products; and

9.2 a licensing regime for domestic cultivation, nursery, manufacturing, supply, and clinical research activities relating to medicinal cannabis.

10 The Scheme has been operational for 3 years and it is now clear that some of the requirements have had unintended impacts on the economic and research activities for industry.

11 The 3 key areas impacting the Scheme are:

11.1 the current definitions of ‘starting material’ and ‘cannabis-based ingredient’ are unnecessarily restrictive and limiting innovation

11.2 the current export settings for medicinal cannabis are a barrier for New Zealand companies to access export markets

11.3 there is no provision to assist New Zealand researchers to use cannabis plant material grown or sourced from the Scheme or industrial hemp framework for research outside the scope of their respective regimes (ie, using medicinal cannabis for other scientific research).

12 Industry stakeholders have indicated that many companies may withdraw from the New Zealand market unless they are able to access the potential economic opportunities from export markets more readily. An unsuccessful domestic industry would be counter to the Government's commitment to improve access to quality medicinal cannabis products.

Regulatory change proposals

Regulatory category definitions under the Scheme

13 Under the Scheme, medicinal cannabis is regulated in 3 categories (starting material, cannabis-based ingredients, and medicinal cannabis products) depending on the stage of manufacturing. The Medicinal Cannabis Regulations specify the types of plant forms (such as dried cannabis or extracts of cannabis) that are permitted in each category. A technical change is required to address feedback that the current categories are restrictive and inconsistent with Good Manufacturing Practice requirements.

14 I propose that the definitions of 'cannabis-based ingredient' and 'starting material' are broadened to account for a wider range of plant material formats in these categories. A new minimum quality standard for 'cannabis-based ingredient' will be introduced to manage risks to product quality associated with dried cannabis when used as a final ingredient.

Cannabis-based ingredient

15 The current definition of 'cannabis-based ingredient' has unintentionally prevented the use of dried cannabis as an ingredient for dosage forms such as oral capsules or tablets. This change will help broaden the range of dosage forms that could be made available under the Scheme.

Starting material

16 Starting material describes raw material used in the manufacturing process and is not intended for direct patient use. A change to capture initial cannabis extracts in this definition would better align with Good Manufacturing Practice requirements and allow companies to use a greater variety of raw material in their manufacturing process.

17 Because of this change, initial extracts from cannabis plant (as starting material) would not be subject to a manufacturing and quality standard. This is a risk proportionate approach because Good Manufacturing Practice manufacturers will continue to have oversight of the quality of raw material used at the start of their processing. This is consistent with a recent regulatory update to the Australian scheme.

Regulatory changes to the minimum quality standard

18 I propose that technical changes are made to improve the workability of the minimum quality standard requirements.

19 The Ministry of Health consulted on the current minimum quality standard requirements in 2019 and refined the standard based on consultation feedback. Since then, there have been developments in alternative tests that could be used to assess product quality and the edition of the *European Pharmacopoeia* referenced in the Medicinal Cannabis Regulations has been superseded. Furthermore, technical areas have been identified where the minimum quality standard could be improved.

Applicability of the minimum quality standard

20 I propose to also clarify that the minimum quality standard only applies to:

20.1 medicinal cannabis intended for therapeutic end use

20.2 cannabidiol (CBD) products intended for human therapeutic use and where the active ingredients are derived from cannabis plant.

21 Currently, the minimum quality standard has been inappropriately applied to activities with medicinal cannabis and all CBD products (including veterinary medicines and where the product is not derived from cannabis). Clarification on when the minimum quality standard applies will ensure other legitimate activities outside the scope of the Scheme are not adversely impacted.

Export settings for medicinal cannabis

22 The current restrictions on export are adding unnecessary costs for local manufacturers and potential exporters by causing the following issues:

22.1 acting as a barrier for cultivators and local manufacturers wishing to access testing, analysis, manufacturing, and research facilities overseas

22.2 preventing local cultivators from exporting cannabis seed to explore export opportunities

22.3 requiring companies to comply with 2 sets of quality standards (New Zealand minimum quality standard and those of the importing country) adds time and cost to the export process.

Exports not related to therapeutic end use

23 I propose the following changes to better assist local companies wishing to access services overseas:

23.1 allow the export of starting material, as fresh or dried cannabis only, without the requirement to meet the minimum quality standard by a holder of a medicinal cannabis licence with a cultivation activity for the purposes of testing, analysis, or research

23.2 exempt exports of starting material, cannabis-based ingredients, and medicinal cannabis products from the requirement to meet the

minimum quality standard by the holder of a medicinal cannabis licence with a supply activity for the purposes of testing, analysis, further manufacturing, or research

23.3 require the exporter to provide evidence to the Agency that the amount to be exported for these purposes is appropriate.

Export of medicinal cannabis seed

24 I propose to allow the export of medicinal cannabis seed under a medicinal cannabis licence with either a cultivation or nursery (seed supply) activity provided the licence holder also holds a licence to export controlled drugs under the Misuse of Drugs Regulations 1977.

25 There are unlikely to be significant risks associated with allowing export of medicinal cannabis seed under the Scheme as the activity will require the importing country to provide appropriate authorisation. This minimises the risk that the seeds will be used for illicit purposes and ensures that international obligations continue to be met.

Export of starting material

26 I propose that the requirement for consignments of starting material to meet the minimum quality standard prior to export be removed to be consistent with the domestic supply of starting material and to make it easier for companies to export. Any quality requirements by the importing country will continue to apply.

27 This proposal will reduce time and costs to the export process. Although this may increase the risk of potentially lower quality material going overseas, it is a risk proportionate approach for how the material will be used. Starting material is not intended for direct patient use but intended to undergo further manufacturing processes (which can subsequently reduce contamination and improve quality).

Export of cannabis-based ingredients and medicinal cannabis products

28 I propose to allow exports of cannabis-based ingredients and medicinal cannabis products without a requirement to meet the minimum quality standard, provided they meet any quality standards specified by the importing country and are manufactured in accordance with Good Manufacturing Practice. The Agency must be satisfied that the importing country has a regulatory authority overseeing the quality of medicinal cannabis otherwise the minimum quality standard will apply.

29 The minimum quality standard was introduced so New Zealand patients can have access to high quality medicinal cannabis products that are free of harmful contaminants. It is not necessary to set standards for other countries' markets if they have already done so. This proposal will assist local manufacturers to compete on a level playing field with overseas companies.

30 Importing countries can regulate the quality of medicinal cannabis through their own import system and local regulatory requirements. Requiring exporters to hold evidence (either through an import licence or letter from the relevant regulatory authority) that their products meet a standard accepted by the importing country ensures New Zealand is a responsible regulator and minimises risks of poor-quality products on patient safety. The licensing framework can ensure that cannabis-based ingredients and medicinal cannabis products are only authorised for export to specific countries.

31 With this change, there is a risk that local companies may choose to manufacture and supply products overseas instead of the New Zealand market which may lead to local supply issues. It is unclear as to whether this risk, and to what extent, is likely to occur. If domestic supply is affected, the Agency can require licence holders to maintain domestic supply, so exports of medicinal cannabis products are not at the detriment of New Zealand patients.

Changes to licensing requirements

General licensing requirements

32 I propose that technical changes are made to the licensing requirements to help provide clarification and to improve the operations of the licensing framework. This includes:

32.1 aligning with existing requirements outlined in the Misuse of Drugs Regulations 1977

32.2 clarifying the intent of some requirements and purpose of research activity

32.3 permitting testing of starting material and cannabis-based ingredient under a possession for manufacture activity

32.4 improving the operations of licensing requirements for CBD product so the regulation can function as intended without impacting on other legitimate activities.

33 This will help ensure that the Scheme is operating as intended.

Nursery activity

34 I propose to refine the nursery activity to the procurement and supply of cannabis seed only and to rename the activity as ‘seed supply’. This will better reflect the intent of the activity.

35 The Ministry of Health consulted on redefining the scope of this activity to allow for the procurement and supply of cannabis seed only. Some stakeholders were concerned that this would eliminate a means of importing and supplying disease free tissue culture and rootstock. However, these activities are already enabled under a cultivation activity which is the most appropriate authorisation for this activity.

Fees

36 I propose that the dosage product assessment fee is amended to $6,700 excluding GST to correct an error in the Medicinal Cannabis Regulations.

37 The current fee of $13,400 (excluding GST) includes the assessment costs for both the cannabis-based ingredient and final dosage product as a single fee. A cannabis-based ingredient can be used in the manufacture for multiple products; therefore, the dosage product fee needs to be corrected to reflect assessment of the final dosage product only. To-date, the Agency has been waiving a portion of the final dosage assessment fee.

Scientific research with cannabis in New Zealand

38 I propose the following changes to remove barriers to research and development with cannabis in New Zealand:

38.1 to allow a licence to possess controlled drugs under the Misuse of Drugs Regulations 1977 to be issued for non-therapeutic research activities involving industrial hemp, provided all other requirements are met

38.2 to allow a licence to possess controlled drugs under the Misuse of Drugs Regulations 1977 to be issued for non-therapeutic research activities using starting material, cannabis-based ingredient and medicinal cannabis products provided all other requirements are met

38.3 to allow holders of a licence to possess controlled drugs to obtain starting material, cannabis-based ingredients and medicinal cannabis products from medicinal cannabis licence holders for analytical and research purposes outside the scope of the Scheme

38.4 to exempt imports of cannabis-based ingredients, medicinal cannabis products and CBD products from the minimum quality standard requirements for research and testing purposes. The importer will need to provide evidence to the Agency that the amount to be imported for these purposes is appropriate.

39 These changes will address gaps in our regulatory framework and provide a licensing pathway for domestically sourced medicinal cannabis and industrial hemp to be used in non-therapeutic research and development. Furthermore, it will ensure that imports for research or testing are not subject to the minimum quality standard requirements which can be prohibitive.

Transitional arrangements

40 I propose to allow medicinal cannabis licences with a nursery activity (being renamed to ‘seed supply’) to remain in effect until the specified expiry date.

Financial Implications

41 There are no financial implications from the proposals in this paper. The current licensing and compliance activities under the Scheme are covered by a cost-recovery model.

42 There are ongoing operational costs for the Agency to oversee the Scheme. These proposed changes are not anticipated to increase the operational costs of the Agency.

Legislative Implications

43 These proposals require amendments to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019, Misuse of Drugs Regulations 1977 and Medicines Regulations 1984.

Impact Analysis

Regulatory Impact Statement

44 The Treasury's Regulatory Impact Analysis team has determined that some proposed changes to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019, 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.

45 The Ministry of Health Quality Assurance panel has reviewed the Impact Statement titled 'Regulatory amendments to improve the economic opportunities of the Medicinal Cannabis Scheme', produced by the Ministry of Health and dated May 2023. The panel considers that the Impact Statement meets the quality assurance criteria. The Impact Statement is clear, complete and consulted. The analysis is balanced in its presentation of the information and impacts are identified and assessed.

Climate Implications of Policy Assessment

46 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to these proposals as the threshold for significance is not met.

Population Implications

47 The implementation of the Scheme, including these changes, will continue to consider equity of access to economic benefits of a medicinal cannabis industry. Māori-owned companies are contributing to the growth of the New Zealand medicinal cannabis industry, including in rural areas with high rates of material deprivation whilst having limited funding and industry experience. Making it easier to export medicinal cannabis would assist Māori-owned companies, and those in established rural communities to compete

internationally. This could improve employment opportunities which could in turn contribute to economic gains and improved health outcomes.

48 In the long term, improving the workability of the Scheme and supporting export opportunities could generate increased income for New Zealand companies to help produce local products that meet the New Zealand domestic standards. This could increase the range of product available on the domestic market and potentially lead to lowered costs for consumers. This is particularly important for people on lower incomes, including Māori and disabled people, as the cost of these products is a key barrier to access.

Human Rights

49 These proposals are consistent with the rights in the New Zealand Bill of Rights Act 1990 and Human Rights Act 1993.

Consultation

50 The Ministry of Health consulted with the following departments and agencies: Te Whatu Ora, Te Aka Whai Ora, Whaikaha, Mental Health and Addiction (Ministry of Health), Department of Prime Minister and Cabinet, Ministry of Business, Innovation and Employment, New Zealand Police, New Zealand Customs Service, Ministry for Primary Industries, Ministry of Foreign Affairs and Trade, Pharmac, Ministry of Justice and the Department of Corrections.

51 The Ministry of Health consulted with medicinal cannabis licence holders, local testing laboratories and the New Zealand Medicinal Cannabis Council in the development of these proposals. Feedback largely supported these proposed changes.

Communications

52 The Ministry of Health will communicate these changes to affected stakeholders once they receive Cabinet agreement.

Proactive Release

53 I intend to proactively release this paper according to standard process under Cabinet Office circular CO (18) 4, subject to redactions as appropriate under the Official Information Act 1982, once the Cabinet decisions come into effect.

Recommendations

The Minister of Health recommends that the Committee:

1 note that the Medicinal Cannabis Scheme was introduced to improve access to quality medicinal cannabis products;

2 note there is an opportunity to improve the Medicinal Cannabis Scheme for industry stakeholders so research and export opportunities can be better supported;

3 note that industry stakeholders have indicated that without regulatory change, it is unlikely that the medicinal cannabis industry will be sustainable in New Zealand's small market;

Medicinal cannabis categories

4 agree to amend the definitions of 'cannabis-based ingredient' and 'starting material' to allow for a broader range of cannabis plant forms;

5 agree to the minimum quality standard for 'cannabis-based ingredient' being amended to address any new risks to product quality for when dried cannabis is used as an ingredient;

The minimum quality standard

6 agree that technical changes will be made to improve and update the minimum quality standard requirements;

7 agree to clarify that the minimum quality standard only applies to cannabidiol products intended for human therapeutic use where the active ingredients are derived from cannabis plant;

8 agree to clarify that the minimum quality standard does not apply to starting material, cannabis-based ingredients or medicinal cannabis products that are not intended for therapeutic end use;

Export of medicinal cannabis

9 agree to allow cannabis seed to be exported as an activity under a medicinal cannabis licence with a cultivation or nursery (seed supply) activity;

10 agree to allow a medicinal cannabis licence holder with a cultivation activity to export samples of starting material without the requirement to meet the minimum quality standard for the purposes of testing, analysis or research;

11 agree to allow a medicinal cannabis licence holder with a supply activity to export starting material, cannabis-based ingredients and medicinal cannabis products for the purposes of testing, analysis, manufacturing or research;

12 agree to remove the minimum quality standard requirement for exports of starting material;

13 agree to allow cannabis-based ingredients and medicinal cannabis products to be exported without meeting the minimum quality standard, provided they are manufactured to Good Manufacturing Practice and the exporter holds evidence that the products are accepted by the importing country;

General licensing requirements

14 agree to technical changes being made to the 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;

Nursery activity

15 agree to amend the nursery activity to allow for the procurement and supply of cannabis seed only, and to rename this activity as 'seed supply';

16 agree to allow a nursery activity on a medicinal cannabis licence to remain in effect until the specified expiry date despite the activity being renamed;

Fees

17 agree to correct the dosage product assessment fee to $6,700 excluding GST to reflect assessment of the final dosage product only;

Scientific research with cannabis

18 agree to allow imports of cannabis-based ingredients or medicinal cannabis products without the requirement to meet the minimum quality standard for the purposes of testing or research;

19 agree to allow a licence to possess controlled drugs to be issued for non-therapeutic research activities using starting material, cannabis-based ingredients, medicinal cannabis products and industrial hemp framework provided all other licencing requirements are met;

20 agree to allow medicinal cannabis licence holders to supply starting material, cannabis-based ingredients and medicinal cannabis products for non-therapeutic research activities with the appropriate authorisation;

Approval for drafting instructions

21 invite the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to the decisions in this paper;

22 agree to authorise the Ministry of Health to consult with a small number of industry experts on a limited exposure draft of the amendments, subject to approval from the Attorney-General.

Authorised for lodgement

Hon Dr Ayesha Verrall

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:

	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

Regulatory Impact Statement: Regulatory amendments to improve the economic opportunities of the Medicinal Cannabis Scheme

Coversheet

Purpose of Document	
Decision sought:	Cabinet decisions on changes to the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 and other technical amendments to improve the workability of the Medicinal Cannabis Scheme
Advising agencies:	Manatū Hauora - Ministry of Health
Proposing Ministers:	Hon Dr Ayesha Verrall, Minister of Health
Date finalised:	*23 May 2023*

Problem Definition

The current export settings for medicinal cannabis are a barrier for New Zealand companies to access export markets and limit the economic opportunities for the medicinal cannabis industry.

There are also several technical changes needed with respect to licensing and the minimum quality standard that can improve the workability of the Scheme. Some of these changes are intended to align some of the requirements under the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 with other existing requirements within the Misuse of Drugs Regulations 1977, Medicines Act 1981 and Medicines Regulations 1984.

Executive Summary

The Medicinal Cannabis Scheme (the Scheme) was introduced on 1 April 2020 through the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 to enable the commercial cultivation of medicinal cannabis domestically, and the manufacture and supply of products made to a quality standard.

Now that the Scheme has been in place for 3 years, it has become clear that some requirements are limiting economic growth within the sector. In the absence of regulatory change, some industry stakeholders have indicated that our local industry will struggle to remain sustainable within New Zealand's small market.

This regulatory impact statement includes a summary of feedback from industry stakeholders on the current export settings and examines options to address key issues that have arisen since the implementation of the Scheme. The preferred options are:

- removing the minimum quality standard requirement for starting material
- removing the minimum quality standard requirement for exports of cannabis-based ingredients and medicinal cannabis products in certain circumstances where the products are manufactured to Good Manufacturing Practice (GMP) and accepted by the importing country.

Both these options allow New Zealand companies to compete on a more level playing field with overseas producers.

Limitations and Constraints on Analysis

Limitations

Targeted stakeholder engagement was conducted on these changes with current medicinal cannabis licence holders, testing laboratories and the New Zealand Medicinal Cannabis Council in lieu of a public consultation. These parties, with their experience of working within the current regulations, were best positioned to comment on the current workability of the Scheme and the potential impact of the proposed changes. However, this has limited our ability to provide insight from those who may have withdrawn from working with the Scheme already and those that may be interested in entering the market with the proposed changes.

Assumptions

The Medicinal Cannabis Agency (the Agency) has only been notified of one consignment of medicinal cannabis products being exported over the last 3 years. Although this demonstrates that the current export requirements are achievable, there is potential for more companies to enter the export market.

It is difficult to quantify precisely how much growth in industry could be achieved by changing the export settings. Respondents did not provide this information and may not have wished to do so for commercial reasons. The analysis of potential impacts for export settings assumes that easier access to export markets will result in an increased number of exports and increased revenue for industry. We assume that this will enable the local industry to be on a more sustainable footing going forward.

The Agency will continue to monitor the number of medicinal cannabis products made available to New Zealand patients to examine if the proposed export settings significantly impact local patient access.

Responsible Manager(s) (completed by relevant manager)

Chris James

Group Manager

Medsafe

Ministry of Health

23 May 2023

Quality Assurance (completed by QA panel)

Reviewing Agency:	Ministry of Health
Panel Assessment & Comment:	The Ministry of Health QA panel has reviewed the Impact Statement titled "Regulatory amendments to improve the economic opportunities of the Medicinal Cannabis Scheme", produced by the Ministry of Health and dated May 2023. The panel considers that the Impact Statement **meets** the quality assurance criteria.

	The Impact Statement is clear, complete and consulted. The analysis is balanced in its presentation of the information and impacts are identified and assessed.

Section 1: Diagnosing the policy problem

What is the context behind the policy problem?

Background to the development of the Medicinal Cannabis Scheme

1. The Misuse of Drugs (Medicinal Cannabis) Regulations 2019 (the Regulations) gave effect to the Medicinal Cannabis Scheme (the Scheme) on 1 April 2020. The purpose of the Scheme is to improve access to quality medicinal cannabis products for New Zealand patients. The Regulations permit the cultivation, manufacture and supply of starting material (raw cannabis plant material), cannabis-based ingredient (active ingredient) and medicinal cannabis products (final products) under a medicinal cannabis licence.

2. Products made available through the Scheme must be manufactured to a high standard so they can be prescribed with confidence. The minimum quality standard manages the risks associated with cannabis-derived products and applies to the following:

    - starting material for export (raw cannabis material)
    - cannabis-based ingredients (active ingredient)
    - medicinal cannabis products
    - cannabidiol (CBD) products.

3. This minimum quality standard specifies the requirements that must be met to ensure the product is of a known, consistent quality, contains the stated amount of active ingredients, and is free from contaminants such as pesticides and heavy metals. Final products are also required to meet further requirements such as for labelling.

4. The minimum quality standard is also applied to cannabis-derived CBD products. CBD, a cannabinoid found in cannabis, has little or no psychoactive properties. CBD products are no longer controlled drugs but remain prescription medicines regulated under the Medicines Act 1981.

5. Cannabis-based ingredients and medicinal cannabis products must be made to Good Manufacturing Practice (GMP). This ensures that good controls are in place during manufacturing and is in line with regulatory best practice for medicines.

Current export settings for starting material, cannabis-based ingredients and medicinal cannabis products

6. Allowing the export of starting material, cannabis-based ingredients and medicinal cannabis products in the design of the Scheme was important, as due to the small size of the New Zealand market it was anticipated that any domestic medicinal cannabis industry would need to look to export opportunities to be sustainable.

7. Raw cannabis plant material must be verified as meeting the minimum quality standard prior to export. Assessment costs $6037.50 for each consignment and verification can take up to 2 months.

8. Although cannabis-based ingredients and medicinal cannabis products must also be verified as meeting the minimum quality standard prior to export, there is no requirement for each consignment to be individually verified.

9. These minimum quality standard requirements were intended to create a high-quality New Zealand medicinal cannabis market.

10. As of April 2023, there have been 12 consignments of starting material verified for export by 5 different companies. To the Agency's knowledge, there has been one consignment of medicinal cannabis product exported. Although this indicates that the current settings are achievable, there is potential for more companies to enter the export market.

How is the status quo expected to develop?

11. The Scheme has been operational for almost 3 years with 29 medicinal cannabis products verified as meeting the minimum quality standard made available to New Zealand patients. Most of these products are imported with only 7 of these products being manufactured domestically. There is significant concern that, despite some initial success with the Scheme so far, certain regulatory barriers are limiting any potential future growth and innovation within the current system.

12. If the current regulation on exports continues, our local medicinal cannabis industry is likely to remain small with a risk that it could eventually decline.

What is the policy problem or opportunity?

13. An unsuccessful local medicinal cannabis industry would ultimately be counterproductive to Government objectives. Introducing domestic cultivation and manufacture of medicinal cannabis products was intended to increase the range of products and ensure that a reliable supply of affordable products is available to New Zealanders.

14. The design and implementation of the Scheme also considers the economic benefits of establishing a medicinal cannabis industry by supporting New Zealand's trade and economic objectives. The current regulation on exports is limiting opportunities for the medicinal cannabis industry to meet these goals.

Problems with the current export settings for medicinal cannabis

15. New Zealand has a small population and therefore the domestic market is relatively small for medicinal cannabis products compared to the international market. Establishing cultivation sites and manufacturing facilities (with GMP accreditation in New Zealand) requires significant capital investment and relying on the New Zealand market alone is insufficient to support the industry.

16. It has now become clear that the current export settings for starting material, cannabis-based ingredients and medicinal cannabis products are creating problems for potential exporters and local manufacturers.

17. New Zealand companies wishing to export medicinal cannabis must comply with the minimum quality standard as well as specifications set by the importing jurisdiction. This adds cost and time to the process for exporters. In some circumstances, this added time impinges on the shelf life of dried cannabis where there is a significant risk that the material could deteriorate before it is exported. Furthermore, some of the specifications within the New Zealand minimum quality standard are different, or more stringent, than the specifications set by the importing country.

18. For example, labelling requirements often differ between jurisdictions. Given the price sensitivity of medicinal cannabis exports, exporters are disadvantaged by only being allowed to export products compliant with New Zealand's labelling requirement.

What objectives are sought in relation to the policy problem?

19. Cabinet has previously agreed to introduce a medicinal cannabis scheme to improve access to quality and affordable medicinal cannabis products for New Zealanders, while supporting New Zealand trade and economic objectives.

20. This can be achieved by ensuring the regulations enable a sustainable local industry.

What do stakeholders think about the problem(s)?

Engagement with stakeholders

21. The Medicinal Cannabis Agency engaged with current licence holders, the New Zealand Medicinal Cannabis Council, and testing laboratories to request feedback on proposed changes (including technical changes) to the Scheme. The engagement email was sent to 61 recipients and the Medicinal Cannabis Agency received 25 responses (16 medicinal cannabis licence holders, 1 industry body, 3 testing laboratories, 5 members of public). The respondents were generally in favour of the proposed changes.

Feedback on current export settings for medicinal cannabis

22. The proposal to remove the minimum quality standard requirements for starting material, cannabis-based ingredients and medicinal cannabis products when exported were strongly supported by local cultivators and manufacturers.

23. The main reasons provided were:

- high costs of complying to 2 different standards (that of New Zealand and the importing country)
- reduced value of exported cannabis products (eg, shortened shelf life) due to the time it takes to show compliance
- material that meets the quality standards of other countries but that does not comply with the New Zealand minimum quality standard cannot be exported
- labelling requirements are a barrier to export of products from New Zealand. Requiring importing customers to remove the New Zealand verified label, carton and leaflet in a GMP facility would render the export of finished product from New Zealand uneconomical.
- the minimum quality standard should not apply to exports of medicinal cannabis samples intended for testing or research purposes
- export of cannabis seed should be allowed within the Scheme to open up further export opportunities.

24. Responses recognised that a quality standard was important to prevent supply of poor-quality material. Most were comfortable with exported cannabis products only being subject to the quality standards of the importing country. Some suggested that reputational risk could be managed by:

- limiting export of un-verified starting material to Pharmaceutical Inspection Co-operation Scheme members
- limiting export of un-verified medicinal cannabis products and cannabis-based ingredients to manufacturers who have GMP.

25. A small number of respondents who disagreed were concerned about:

- reputational risks – some supported a reduction, but not removal, of some minimum quality standard requirements
- difficulty for overseas buyers in distinguishing verified and un-verified New Zealand medicinal cannabis products
- the need to establish recall procedures by companies for exported products.

Section 2: Deciding upon an option to address the policy problem

2A: Export requirements for starting material

What criteria will be used to compare options to the status quo?

26. The following criteria have been used to compare options for changing export requirements for starting material:

- impact on New Zealand's reputation
- protects patient safety
- quality requirements are proportionate to the level of risk
- compliance requirements enable the development of a sustainable domestic medicinal cannabis industry

What options are being considered?

Option One – *Status quo*

27. Exporters of starting material must demonstrate that each consignment meets the minimum quality standard.

Option Two – *Removing the requirement for each consignment of starting material for export to meet the New Zealand minimum quality standard*

28. Starting material can be exported without first demonstrating that the consignment meets the New Zealand minimum quality standard. Any quality standards required by the importing country will continue to apply.

How do the options compare to the status quo?

	Option One – *Status quo*	Option Two – *Removing the requirement for each consignment of starting material for export to meet the New Zealand minimum quality standard*
Impact on New Zealand's reputation	0 Protects New Zealand's reputation as a producer of high-quality material	- May negatively affect New Zealand's reputation and access to markets if poor quality material is exported. Removes ability for some companies to use the New Zealand minimum quality standard as a point of difference.
Enabling sustainable development of the domestic medicinal cannabis market	0 Limited exports from New Zealand companies	++ Applies standards that are relevant to the importing country and overseas manufacturer. Reduces compliance costs and time for industry stakeholders to access export markets. Likely to increase number of exports, including from smaller companies.
Quality requirements are proportionate to level of risk	0	+ Risk proportionate approach. Starting material is intended to be further processed and not for direct human use.
Protects patient safety	0 Prevents sub-optimal starting material reaching overseas.	0 May reduce product quality for *overseas* patients. No impact on product safety in New Zealand. Material will still be required to meet any standards set by importing country.
Overall assessment	0	++

Key:

++	much better than doing nothing/the status quo
+	better than doing nothing/the status quo
0	about the same as doing nothing/the status quo
-	worse than doing nothing/the status quo
- -	much worse than doing nothing/the status quo

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

29. The preferred option is *Option Two*, which removes the requirement for starting material to meet the New Zealand minimum quality standard for export. This option recognises that different manufacturers and importing countries will have and may set different specifications. This option will better support cultivators, especially smaller companies, with accessing export markets and reduce compliance costs.

30. Although there may be a risk that the exported material could be of poorer quality, this option is a reasonable and a risk-proportionate approach to how starting material is intended to be used. Starting material is intended to undergo further processing, which can subsequently reduce contamination and improve quality. It is not necessary to set a high-quality standard for raw cannabis plant material at the point of export.

31. Most medicinal cannabis cultivation sites are in rural or semi-rural locations within New Zealand. If removing the minimum quality standard for exported starting material improves access to export markets for New Zealand cultivators, this will likely confer greater benefits to rural communities where a significant proportion of medicinal cannabis cultivation occurs currently. The trade and economic benefits could potentially translate to improved health outcomes in these communities which have higher levels of material deprivation.

32. Most stakeholders agreed with the removal of the minimum quality standard from exports of starting material. A small number of stakeholders disagreed, arguing that the New Zealand quality standard for starting material was a 'point of difference'. However, New Zealand companies can still choose to continue to meet the specifications within the minimum quality standard if that is what the export market or importing country desires. The difference with the proposed approach is that the specifications will no longer be a requirement that all exported raw material must meet. The risk is outweighed by the potential benefits of making the export markets more accessible.

What are the marginal costs and benefits of the option?

Affected groups	Comment	Impact	Evidence Certainty
Additional costs of the preferred option compared to taking no action			
Regulated groups	Cost Compliance costs (ongoing) Compliance requirements/ administrative burden (ongoing)	High High	High *Companies will no longer need to have their consignments verified at $6037.50 per consignment.* High *Companies only need to meet one set of requirements (importing country or overseas manufacturer). This reduces time and resourcing as well as increasing supply chain efficiency.*
Regulators	Cost Compliance cost (ongoing)	Medium	Low *Using the assumption that removing the minimum quality standard will make it easier for companies to export, this may increase the number of consignments of starting material each year.*
Total monetised costs		Not applicable	
Non-monetised costs		*High*	
Additional benefits of the preferred option compared to taking no action			
Regulated groups	Establishment of trade opportunities with overseas jurisdictions	High	Medium *Exporters will be able to further establish relationships and build a market for their starting material with overseas jurisdictions.*
Regulators	Not applicable	Not applicable	Not applicable
Rural communities	Increased trade and economic benefits from accessing export markets that could potentially be shared with surrounding communities	High	Medium *This is dependent on where these companies are established. Currently, most licensed cultivation sites are established in rural or semi-rural communities.*
Government	Supporting the sustainability of the industry in both domestic and international markets	Medium	Medium *Allowing easier export of starting material will ensure that the domestic medicinal cannabis market is able to sustainably develop.*
Total monetised benefits		Not applicable	

Non-monetised benefits		*High*	

2B: Export of cannabis-based ingredient and medicinal cannabis products

What criteria will be used to compare options to the status quo?

33. The following criteria have been used to compare options for changing export requirements for starting material:

- impact on New Zealand's reputation
- protects patient safety
- quality and manufacturing requirements are proportionate to the level of risk
- compliance requirements enable the development of a sustainable domestic medicinal cannabis industry that includes small and large stakeholders.

What scope will options be considered within?

34. Any option considered must have regard to addressing risks to patient safety from poor-quality products reaching international markets.

What options are being considered?

Option One – *Status quo*

35. Domestically manufactured cannabis-based ingredients and medicinal cannabis products must be verified as meeting the minimum quality standard before they can be exported.

Option Two – *Remove the requirement for cannabis-based ingredients and medicinal cannabis products to meet the New Zealand minimum quality standard if it meets the quality requirements of the importing country*

36. In this option, New Zealand would not impose its domestic quality standard requirements on exports of cannabis-based ingredients and medicinal cannabis products, provided the exporter holds evidence that it meets any quality requirements set by the regulatory authority of the importing country. These exported products must continue to be manufactured to GMP.

How do the options compare to the status quo?

	Option One – *Status quo*	Option Two – *remove the requirement for cannabis-based ingredients and medicinal cannabis products to meet the minimum quality standard, if it meets the quality requirements of an importing country*
Impact on New Zealand's reputation	0 Ensures that only products of a high quality are exported.	- Increased risk of low-quality products being exported overseas which may negatively affecting New Zealand's reputation as an exporter of high-quality products. This would be a risk in countries with significantly lower standards than New Zealand.
Protects patient safety	0 Ensures that only products of a high quality are exported.	0 No impact on the quality of product prescribed to New Zealand patients. May impact on the quality of products supplied to *overseas* patients but products would still need to meet any quality requirements set by local authorities.
Quality and manufacturing requirements are proportionate to level of risk	0 Quality and manufacturing requirements for export may exceed or be different to quality requirements of import country.	+ Quality and manufacturing standards applied to exported products are reflective of the regulatory expectations and risk assessment of importing country, including labelling.
Enables development of a sustainable domestic medicinal cannabis industry	0 Little to no export of products occurring. Local companies unable to remain sustainable in New Zealand market.	++ Allows New Zealand companies to compete on a level playing field with overseas companies. Potential for increased exports and revenue. Easier access to export markets may allow for economies of scale where products could be made in larger quantities for a cheaper price. Reduced compliance costs as some exported products will no longer need to meet two sets of standards.
Overall assessment	0	++

Key:

++	much better than doing nothing/the status quo
+	better than doing nothing/the status quo
0	about the same as doing nothing/the status quo
-	worse than doing nothing/the status quo
- -	much worse than doing nothing/the status quo

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

37. The preferred option is *Option Two* which removes the requirement for exports of cannabis-based ingredients and medicinal cannabis products to meet the New Zealand minimum quality standard in certain circumstances, provided the exporter holds evidence that it meets any quality requirements set by the regulatory authority of the importing country. This option balances the need to ensure exported products are of a suitable quality and to better support local companies entering export markets.

38. Feedback from industry supported an approach where they would only have to comply with the quality standards of the importing country. This would reduce time and costs, and provides additional markets for New Zealand companies to trade in.

39. To date, the Agency is only aware of one consignment of medicinal cannabis products having been exported. This option would likely help increase the number of exports by New Zealand companies. Delivering more support for export opportunities will help local industry be on a more sustainable footing going forward and ensure that our industry can compete on a level playing field internationally. This would support New Zealand's trade objectives.

40. Smaller scale companies, without GMP facilities, would likely not benefit directly from this regulatory change but could look to contract licensed manufacturers to manufacture a product to specification for export or focus on supplying starting material to manufacturers.

41. There are some risks with this option. There is potential for New Zealand's reputation to be damaged if poor quality medicinal cannabis products were sold overseas and some respondents were concerned that a small number of poor-quality exports could ruin the industry for all. However, this would only be a risk in jurisdictions which do not enforce quality standards or have significantly lower quality standards. The Medicinal Cannabis Agency will prevent this by restricting exports to countries where there are established systems that regulate the quality of medicinal cannabis products and require exporters to provide evidence that the relevant authority of the importing country has confirmed its willingness to accept the quality of products.

42. In some cases, *Option Two* may result in fewer locally produced products being available to New Zealand patients. Local companies may choose to supply internationally rather than to the New Zealand market where the minimum quality standard remains. It is difficult to predict if this would occur and to what extent, however, the possible expansion of domestic industry is expected to outweigh this risk. Industry feedback has indicated that without easier access to export markets, local companies are likely to be unsustainable which may lead to little or no availability of locally produced products. If this does occur, the Agency can require licence holders to ensure that they maintain domestic supply requirements. This will ensure that the changes to export requirements do not negatively impact the supply of product to New Zealand patients. Currently most products, which are verified as meeting the minimum quality standard, are imported and we expect the provision of imported products to continue under these changes.

What are the marginal costs and benefits of the option?

Affected groups	Comment	Impact	Evidence Certainty
Additional costs of the preferred option compared to taking no action			
Regulated groups	Benefit (ongoing) Increased revenue from exports of cannabis-based ingredients and medicinal cannabis products overseas Cost (ongoing) Exporters to provide evidence that importing country has accepted quality of medicinal cannabis products	High Low	High *Many companies have indicated that export markets are important to remaining sustainable in New Zealand.* High *The proposed new requirement is for exports to meet the quality standard of the importing country.*
Regulators	Cost (one-off) Regulator to work with stakeholders to determine which regulatory authorities oversee quality of medicinal cannabis	Low	High *Necessary for regulator to establish which markets regulate the quality of medicinal cannabis.*
Total monetised costs			
Non-monetised costs		*Low*	
Additional benefits of the preferred option compared to taking no action			
Regulated groups	Opportunities for product development and establishing networks with international markets	High	Medium *Exporters will be able to produce cannabis-based ingredients and medicinal cannabis products which are appropriate for the market they are producing for. This may also improve relationships and the ability to establish sustainable relationships with export markets.*
Regulators	Not applicable		
Consumers	May result in fewer products being available in New Zealand (risk)	Low	Low *This is dependent on commercial decisions by regulated parties. However, the status quo could ultimately lead to no domestically available products if industry is no longer financially or commercially viable.*
Government	Sustainability of the Medicinal Cannabis	Medium	Medium

	Scheme is in line with Government objectives		*New Zealand will be able to clearly establish itself in the export markets for medicinal cannabis which is in line with trade objectives*
Total monetised benefits			
Non-monetised benefits		*Medium-High*	

Section 3: Delivering an option

How will the new arrangements be implemented?

43. The new arrangements will be communicated to affected stakeholders by the Medicinal Cannabis Agency. Guidance documents will be updated to reflect the new requirements and to assist regulated parties with complying with the new requirements. This is an existing function of the regulator and is not expected to require additional funding or resourcing. The Agency will be responsible for developing and implementing new operational policies to address the changes.

How will the new arrangements be monitored, evaluated, and reviewed?

44. The Medicinal Cannabis Agency and the Ministry of Health will monitor the number of exported medicinal cannabis consignments and products made available to New Zealand patients once the changes are implemented to evaluate whether access to locally produced products is adversely impacted.