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	<u>Benefit (ongoing)</u> Increased revenue from exports of cannabis-based ingredients and medicinal cannabis products overseas <u>Cost (ongoing)</u> 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	<u>Cost (one-off)</u> 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.