Appendix 1 - Medicinal Cannabis Scheme: Public consultation and establishing a new medicinal cannabis agency

In Confidence

Office of the Minister of Health

Chair, Cabinet Social Wellbeing Committee

Medicinal Cannabis Scheme: Public Consultation and establishing a medicinal cannabis agency

Proposal

1. This paper seeks Cabinet approval to publicly consult on the requirements for the Medicinal Cannabis Scheme and to establish the medicinal cannabis agency within the Ministry of Health as the regulator.

Executive Summary

2. Cabinet agreed on 6 December 2017 (CBC-17-MIN-0043) to introduce a Medicinal Cannabis Scheme (the Scheme) that will enable commercial cultivation and manufacture. The Scheme aims to improve patient access to quality medicinal cannabis products.

3. Social Wellbeing Committee agreed on 12 December 2018 (SWC-18-MIN-0195) that the Scheme will include a licensing regime for the cultivation of cannabis for medicinal use, and the manufacture and supply of medicinal cannabis products. All medicinal cannabis products supplied under the Scheme will be required to meet quality standards. These requirements reflect the requirements for other medicines and are necessary to ensure prescriber confidence and patient safety.

4. The attached consultation paper sets out the details of the Scheme and provides an opportunity for the Ministry of Health to seek feedback from the public, industry, healthcare professionals and other interested stakeholders on the proposals. The consultation paper focuses on the:
    a. proposed quality standards which may apply to cultivation and manufacture processes and to final products
    b. licensing requirements which apply to all stages of production through to supply
    c. prescribing requirements
    d. proposed requirements after the medicinal cannabis product goes to market
    e. fees and charges.

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5. This feedback will help shape the regulatory proposals needed to support the Scheme. I will report back to Cabinet in October 2019, following consultation, with the final proposals for the Scheme. There is a statutory requirement for the regulations to enable the Scheme to be made by 18 December 2019.

6. A medicinal cannabis agency (the agency) is required to oversee the Scheme. I propose establishing the agency within the Ministry of Health, which will have the ability to cost recover via licensing fees. Further details on the agency are provided in paragraphs 40-43.

Background

7. The term 'medicinal cannabis' can mean different things to different people. For the purposes of the Medicinal Cannabis Scheme, it means a product that is accessed by a patient via prescription.

8. Currently, medicinal cannabis products are available on prescription. However, there is a lack of affordable products made to a quality standard available in New Zealand. This has led to some patients accessing cannabis through the illicit market, with concerns about poor quality of products, continuity of supply, unknown consistency of cannabinoid content, fear of prosecution and unregulated high prices. This increases risks to patients.

9. In December 2017 the Government made a commitment to improve access to affordable, quality medicinal cannabis products and agreed to introduce a Scheme that would enable the commercial cultivation of cannabis for medicinal purposes, and the manufacture of medicinal cannabis products made to a quality standard.

9. A key feature of the Scheme is to provide health practitioners, and the people who will use the products, with confidence about the range of quality medicinal cannabis products available to them. A strong regulatory system, with controls on the cultivation, manufacture and supply of medicinal cannabis products will provide this.

Referendum on recreational use

10. Legalisation of cannabis for recreational use is outside the scope of the Scheme, but will be the subject of a referendum to be held by 2020. It is expected that many in the medicinal cannabis industry will look to also produce for a recreational scheme, if this goes ahead following the 2020 referendum.

Public consultation on the Medicinal Cannabis Scheme

11. I want to be sure that the Scheme can meet the Government's intent to improve patient access to affordable, quality medicinal cannabis products, and support equitable health outcomes.

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12. To increase access to quality products, the Scheme must enable the cultivation and manufacture of medicinal cannabis products in New Zealand, and the import of overseas products. It must also provide health practitioners with confidence about the range of quality medicinal cannabis products available.

13. The regulatory requirements for the Scheme should balance the need for quality products, which have compliance costs for industry, with the need for affordable products.

14. The consultation paper sets out the details of the Scheme and provides an opportunity for the Ministry of Health to seek feedback from the public, industry, health professionals and other interested stakeholders on:

    a. proposed quality standards which may apply to cultivation and manufacture processes and to final products

    b. licensing requirements which apply to all stages of production through to supply

    c. prescribing requirements

    d. proposed requirements after the medicinal cannabis product goes to market

    e. fees and charges.

15. The feedback received through consultation will inform the regulatory proposals to support the Scheme. I intend to bring these proposals back to Cabinet in October 2019.

Quality standards

16. A key element of the Scheme is the introduction of a requirement for all medicinal cannabis products to meet minimum quality standards for:

    - cultivation
    - manufacture
    - active pharmaceutical ingredients
    - finished products.

17. The requirement for products to meet quality standards and what those standards should be, are likely to be a key focus of consultation feedback.

18. The proposed *quality standards for manufacture* may attract the most attention during consultation. Manufacturing standards are necessary to ensure products are consistently produced. There is a risk that the sample results from the finished product testing would not accurately represent the whole batch of products, if manufacturing quality standards are not required. In addition, manufacturing standards minimise the risks of unexpected contamination of products, incorrect labelling of products, and insufficient or too much active ingredient.

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19. The consultation document sets out two options for the manufacture of medicinal cannabis under the Scheme: a. Good Manufacturing Practice for medicine (GMP), and b. Good Production Practices (GPP).

    a. GMP is the internationally recognised standard for manufacture of medicines. Most countries (including Australia, Japan and those in the European Union) require manufacture of medicinal cannabis products to meet GMP for medicines.

    b. GPP is used in Canada for the manufacture of non-prescription medicinal cannabis, in the form of fresh, dried and oils. This manufacturing standard is included as some stakeholders have asked for an alternative manufacturing option to GMP to potentially enable more products to enter the market, while maintaining an acceptable minimum quality standard.

20. The consultation document seeks feedback on:

    - the level of industry interest in a New Zealand GPP pathway (in addition to the existing GMP pathway), and
    - whether health practitioners would confidently prescribe, and patients use, products manufactured to GPP.

Licensing

21. Like other controlled drugs that are used as medicines, the Scheme requires all stages of medicinal cannabis production to be licenced, including:

    - cultivation
    - manufacture
    - supply
    - import and export.

22. Some general requirements for licence holders may attract attention during consultation. For example, under the Misuse of Drugs Act all licence holders are assessed against a *fit and proper person* test.

23. The purpose of the fit and proper person test is to ensure the licence holder has the knowledge and expertise to undertake the licenced activity, and poses minimal risk of abusing or diverting cannabis. Police vetting is required for all applicants.

24. Some stakeholders have raised concerns that this test could exclude people with a history of drug convictions from the industry. The consultation document proposes that the fit and proper person test applies to licence holders, and not all employees. This is the same approach used for other controlled drug licence holders such as wholesalers and pharmacies.

25. The consultation document seeks feedback on the proposed requirements for licence holders.

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Prescribing requirements

26. Medicinal cannabis products are only available on prescription and this requirement will continue under the Medicinal Cannabis Scheme. The prescriber assesses the risks and benefits of a particular product for a particular patient.

27. Currently, pre-approval to prescribe from the Minister of Health (delegated to the Ministry of Health), is required for most medicinal cannabis prescriptions that contain THC. Doctors are able to prescribe Sativex for its consented use (as an add-on treatment in Multiple Sclerosis) without approval from the Ministry.

28. The consultation document seeks feedback on proposals to reduce and/or remove the requirement for the Minister of Health (delegated to the Ministry) pre-approval to prescribe medicinal cannabis products containing THC when the products meet the quality standards of the Scheme.

Post Market Controls

29. A medicinal cannabis agency will be established as the regulator to oversee the Scheme (refer to paragraphs 40-43). The regulator will continually monitor and evaluate the safety and quality of medicinal cannabis products on the market and manage any risks of harm associated with individual products.

30. As for other medicines, manufacturers and suppliers distributing medicinal cannabis products will be required to have a complaints and recalls process in place before they are granted a medicinal cannabis licence.

31. In addition, the regulator will have the ability to vary, suspend or revoke licences, where licence conditions are not met, or on the grounds of concern about product safety or quality. The regulator will also have the ability to impose penalties for non-compliance with relevant product quality standards, with relevant product information requirements or with licence conditions. This aligns with the existing approach for licensing of manufactures and suppliers of other medicines.

32. The consultation document seeks feedback on the proposals for post market controls on medicinal cannabis products.

Fees and charges

33. The proposed licensing regime for the Scheme will include fees for:

- cultivation of cannabis (with a separate fee for declarations of illicit seed)
- manufacture of medicinal cannabis products (including active pharmaceutical ingredients)
- supply of medicinal cannabis products with a separate fee for the assessment by the regulator that final products meet the New Zealand monograph requirements.

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34. The proposed licence fees have taken into consideration the principles outlined in the Treasury *Guidelines for Setting Charges in the Public Sector (2017)* and are calculated based on full recovery of the direct costs associated with the specific licensed activities.

35. For GMP manufacture, licences to manufacture medicines will be issued under the Medicines Act and the existing schedule of fees will apply.

36. If GPP is used as the manufacturing standard then licences to manufacture will be issued by the agency (refer to paragraphs 40-43). The fees for each licence would be based on the direct time and costs associated with:

    - assessment of application, including Police vetting
    - on-site audits associated with application
    - monitoring that the licence holder is compliant with the licence conditions.

37. Estimations show that the GPP fees for a licence to manufacture and for a licence to pack would be substantially higher than for GMP. The cost difference is due to: the cost of training auditors to a bespoke standard; a smaller pool of manufacturers to spread costs across; and because the GMP fees are currently under-cost recovered (these are already set under the Medicines Act 1981).

38. If a GPP manufacture standard is supported, the Government may wish to consider providing funding to off-set the GPP manufacture licensing costs (ie funding the auditor training costs). I will provide advice on this in the October Cabinet paper.

39. The consultation document seeks feedback on the proposed licence fees for cultivation, declaration of illicit domestic seed, product assessment and import/export licences.

Establishment of a medicinal cannabis agency

40. An agency must be established to licence cultivation of medicinal cannabis to comply with the United Nations Single Convention on Narcotic Drugs 1961. The Single Convention requires cultivation of medicinal cannabis to be undertaken under a government issued licence.

41. I wish to set this up now to ensure that the Scheme is able to be operationalised in the first quarter of 2020.

42. I propose establishing an agency within the Ministry of Health as the regulator, as it is the most effective and efficient mechanism to enable the Scheme. The Ministry of Health already licences controlled drugs used for a therapeutic purpose, other therapeutic products, and other uses of cannabis (for example, industrial hemp, and low-THC hemp seeds as food). The Ministry can also use existing knowledge and expertise, and ensure requirements across therapeutic products and controlled drugs are consistent and coherent.

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43. The functions of the agency will include (but are not limited to):

    a. overseeing the licensing of growers, processors, manufacturers, importers, exporters and wholesale distributers of medicinal cannabis products

    b. monitoring compliance with licence conditions, including the requirement for cannabis products to meet quality standards

    c. post market monitoring of unconsented medicinal cannabis products for adverse events

    d. collecting and reporting on data to the International Narcotic Control Board about medicinal cannabis production and use in New Zealand

    e. providing information to prescribers about products that meet the quality standards, and

    f. monitoring of the Scheme to ensure it is achieving its objectives.

Medicinal Cannabis Advisory Group

44. A Medicinal Cannabis Advisory Group was established in March this year to provide advice to the Ministry of Health during the establishment and implementation of the Scheme. The proposals set out in the consultation document have been considered by the Medicinal Cannabis Advisory Group.

45. The Advisory Group is chaired by Dr Russell Wills who was New Zealand's Children's Commissioner for five years until June 2016. Dr Wills is currently a community and general paediatrician and Medical Director of Quality Improvement and Patient Safety at the Hawke's Bay District Health Board in Hastings.

46. Other members of the Advisory Group have health practitioner (medical, nursing and pharmacy), research, regulatory, industry and consumer experience and expertise.

47. There were a range of views across the Advisory Group on the minimum quality standards for production and final products, and the prescribing requirements under the Scheme. Discussions were focussed on the level of risk posed by unconsented products, the level of clinical oversight needed and the strong desire for improved patient outcomes and equity of access.

48. The Advisory Group will be briefed on the consultation feedback and have an opportunity to provide input on the final proposals for the design of the Scheme before I report back to Cabinet.

Next steps

49. The consultation paper will be released in July 2019 for five weeks. Following consultation and analysis of feedback, I will report back to Cabinet in October 2019 with final proposals on the detail of the Scheme. I will also be seeking agreement to instruct Parliamentary Counsel Office to draft the Regulations.

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Consultation

50. The Ministry has consulted with the following agencies: DPMC (Policy Advisory Group), NZ Police, Ministry of Justice, New Zealand Customs Service, ACC, Te Puni Kōkiri, Treasury, *Ministry for Pacific Peoples*, *Oranga Tamariki – Ministry for Children*, Ministry for Primary Industries, Ministry of Business Innovation and Employment, State Services Commission and PHARMAC.

Financial Implications

51. The Ministry received $1.118 million from the 2018 between-Budget contingency to undertake establishment activities in 2018/19 and 2019/20. It is expected that the ongoing operating costs will be approximately $0.650 million per year over the first five years of the Scheme.

52. I want to enable the Scheme to be able to cost recover. However, depending on the size of the medicinal cannabis industry and the manufacturing options allowed under the Scheme, there may be a need for additional funding from Government.

53. As part of my report back to Cabinet in October 2019, I will provide further information about how the Scheme will be funded. This is expected to be through a mix of fees, and ongoing appropriations requested in Budget 2020.

Human Rights

54. The proposals are consistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Legislative Implications

55. Regulations will be needed to fully implement the scheme.

Impact Analysis

56. The Regulatory Quality Team at The Treasury considers that an impact assessment is not required. This exemption is approved on the condition that the consultation paper contains the elements of a Regulatory Impact Assessment, and that this is verified by the Ministry of Health's Regulatory Impact Assessment Panel or quality assurance expert.

Gender Implications

57. There are no gender implications associated with these proposals.

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Disability Perspective

58. The intent of the proposed Scheme is to improve access to medicinal cannabis products for patients with significant conditions (for example multiple sclerosis), who do not respond to conventional treatments, as and when the products are available.

Publicity

59. The public consultation for the Medicinal Cannabis Scheme will be run through the Ministry of Health's Consultation Hub using the online tool Citizen Space. The consultation launch and accompanying media coverage will be followed by targeted information sessions for different stakeholder groups, including industry, the medical community, researchers and consumers.

Proactive Release

60. I intend to proactively release this paper, following Cabinet approval.

Recommendations

The Minister of Health recommends that the Committee:

1. **note** that on 6 December 2017, the Cabinet Business Committee agreed (CBC-17-MIN-0043) to introduce a Medicinal Cannabis Scheme that enables commercial cultivation and manufacture of medicinal products made to a quality standard in a timely way, including the establishment of an agency

2. **note** that on 12 December 2018, Social Wellbeing Committee agreed (SWC-18-MIN-0195) that the Medicinal Cannabis Scheme would include licensing of all stages of production and supply, and that all products would have to meet minimum quality standards

3. **note** that the objective of the Medicinal Cannabis Scheme is to improve access to quality medicinal cannabis products

4. **note** that the consultation document sets out the detail of the Medicinal Cannabis Scheme and seeks feedback on the proposed requirements including:

    a. proposed quality standards which may apply to cultivation and manufacture processes and to final products

    b. licensing requirements which apply to all stages of production through to supply

    c. prescribing requirements

    d. proposed requirements after the medicinal cannabis product goes to market

    e. fees and charges.

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5. **agree** to the public release of the Medicinal Cannabis Scheme Consultation Document in July 2019

6. **agree** that the Minister of Health can approve minor technical and editorial amendments to the consultation document prior to its public release

7. **note** that following assessment of the consultation feedback, I will report back to Cabinet with final recommendations for requirements of the Medicinal Cannabis Scheme in October 2019 and seek approval for PCO to draft regulations

8. **note** that there is a statutory requirement for the regulations to be made by 18 December 2019

9. **agree** that the medicinal cannabis agency is established within the Ministry of Health.

Authorised for lodgement

Hon Dr David Clark

Minister of Health

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SWC-19-MIN-0078

Cabinet Social Wellbeing Committee

Minute of Decision

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Medicinal Cannabis Scheme: Release of Consultation Document

Portfolio Health

On 26 June 2019, the Cabinet Social Wellbeing Committee (SWC):

1 **noted** that on 6 December 2017, the Cabinet Business Committee agreed to introduce a Medicinal Cannabis Scheme that enables the commercial cultivation and manufacture of medicinal products made to a quality standard in a timely way, and to the establishment of an agency [CBC-17-MIN-0043];

2 **noted** that on 12 December 2018, SWC agreed that the Medicinal Cannabis Scheme would include licensing of all stages of production and supply, and that all products would have to meet minimum quality standards [SWC-18-MIN-0195];

3 **noted** that the objective of the Medicinal Cannabis Scheme is to improve access to quality medicinal cannabis products;

4 **noted** that the consultation document, attached to the submission under SWC-19-SUB-0078, sets out the detail of the Medicinal Cannabis Scheme and seeks feedback on the proposed requirements including:

4.1 quality standards which may apply to cultivation and manufacture processes and to final products;

4.2 licensing requirements which apply to all stages of production through to supply;

4.3 prescribing requirements;

4.4 proposed requirements after the medicinal cannabis product goes to market;

4.5 fees and charges;

5 **agreed** to the public release of the Medicinal Cannabis Scheme consultation document in July 2019;

6 **authorised** the Minister of Health to approve minor technical and editorial amendments to the consultation document prior to its public release;

7 **noted** that, following assessment of the consultation feedback, the Minister of Health will report to SWC in October 2019 with final recommendations for the requirements of the Medicinal Cannabis Scheme, and to seek approval for the Parliamentary Counsel Office to draft regulations;

8 **noted** that there is a statutory requirement for the regulations to be made by 18 December 2019;

9 **agreed** that a medicinal cannabis agency be established within the Ministry of Health.

Gerrard Carter
Committee Secretary

Present:
Hon Phil Twyford
Hon Chris Hipkins
Hon Andrew Little
Hon Dr David Clark
Hon Nanaia Mahuta
Hon Stuart Nash
Hon Tracey Martin (Chair)
Hon Peeni Henare
Jan Logie, MP

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

Hard-copy distribution:
Minister of Health

CAB-19-MIN-0329

Cabinet

Minute of Decision

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Report of the Cabinet Social Wellbeing Committee: Period Ended 28 June 2019

On 1 July 2019, Cabinet made the following decisions on the work of the Cabinet Social Wellbeing Committee for the period ended 28 June 2019:

Out of scope

Out of scope

[redacted]

SWC-19-MIN-0078 **Medicinal Cannabis Scheme: Release of Consultation Document** CONFIRMED

Portfolio: Health

Out of scope

[redacted]

Michael Webster
Secretary of the Cabinet

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