7 August 2019 Our ref: LH19-370

Ministry of Health
PO Box 5013
WELLINGTON 6140

via email: medicinal_cannabis@health.govt.nz

Tēnā koutou katoa,

Medicinal Cannabis Scheme consultation

Thank you for giving The Royal New Zealand College of General Practitioners the opportunity to comment on the Medicinal Cannabis Scheme consultation.

Our kaupapa is to set and maintain education and quality standards for general practice and support our members to provide competent, equitable care to their patients. We do this to improve health outcomes and reduce health inequities.

General practitioners comprise almost 40 percent of New Zealand's specialist workforce and their professional body, The Royal New Zealand College of General Practitioners (the College), is the largest medical college in the country. We will continue to advocate on behalf our vocationally registered GPs and their clinical expertise as specialists to prescribe medicinal cannabis under the correct conditions as a potential therapeutic option.

The College has previously endorsed the New Zealand Medical Association (NZMA) position statement on medicinal cannabis[1]. It strongly believes that Medsafe, Pharmac and ultimately the Ministry of Health are the only appropriate organisations to develop standards for funding, prescribing and usage of medicinal cannabis.

The current public and government support for this emerging industry and therapeutic option, including the subsequent controls of process, supply and manufacturing currently outweigh the clinical research into the efficacy of cannabis specifically as a medicinal product.

The College recommends the immediate shift of this balance to firstly focusing on the evidence base for therapeutic use of cannabis products in the health sector, and the education of consumers. There needs to be clear boundaries between the proposed changes in legislation on medicinal cannabis and recreation use of cannabis products.

In our response to the Misuse of Drugs (Medicinal Cannabis) Amendment Bill[2], the College recommended the following points:

[1] New Zealand Medical Association. 2017. *Medicinal cannabis position statement.* Accessed 5 August 2019. https://www.nzma.org.nz/__data/assets/pdf_file/0009/77958/Medicinal-cannabis-position-Statement_November-2017.pdf

[2] RNZCGP. 2018. *Misuse of Drugs (Medicinal Cannabis) Amendment Bill submission.* Accessed 5 August 2019. https://www.rnzcgp.org.nz/RNZCGP/Advocacy/Misuse_of_Drugs_medicinal_cannabis_bill.aspx

- A cannabis product must meet Medsafe's criteria to be classed as a medicine.
- The Government facilitates training for medical practitioners, with training on changes to the law and discussing the harms and benefits of therapeutic and illicit cannabis use.
- The Committee considers how a patient consultation will align with the Health and Disability Services Consumers' Rights, particularly Right 6 – the right to be fully informed.
- The Government should facilitate research on the medical potential of cannabis, as this will allow for a larger evidence base to make informed decisions.
- The Committee considers how the medicinal cannabis scheme may work with the Therapeutics Bill.

Medicinal Cannabis Scheme Proposals

Quality standards for medicinal cannabis products (Part B)

Proposal B2 The College does not support option A (manufacturers would determine the desired quality for the starting material) as a suitable choice.

Proposal B3 The College agrees with Option A, to adopt the current New Zealand approach for manufacturing in accordance with Good Manufacturing Practice (GMP) (Medicines Act) for all medicinal cannabis products.

Proposal B4 The College agrees with the proposal that all active pharmaceutical ingredients should be required to meet the requirements of the New Zealand Product Quality Standards Monograph (Appendix 2). Additionally, we agree with the current recommendations of dose form(s), product specification and testing to meet quality standards.

We would advocate for the highest level of quality, based on Good Agricultural Practice, GMP or the New Zealand Product Quality Standards Monograph, to guarantee patient safety from production and manufacturing through to product consumption as a prescribed medicine. In addition, the College would like to restate that all cannabis products must meet Medsafe's criteria to be classed as a medicine to ensure they are subject to the same pharmacovigilance as other medicines.

The reference to Canadian systems of lesser stringent batch control is worrying and the continued reference through the proposals of using a Canadian system concerns the College as there is not enough evidence-based contextualisation for New Zealand.

Licensing under the Scheme (Part C)

Proposal C3 The College agrees with the principles proposed for general licensing.

Proposal C4 The College has no position on the supply of seeds, number of cultivation sites or definition of small-scale and large-scale cultivation.

Proposal C5 The College has no position on limits on the amount of seed or number of declarations that could be allowed.

Proposal C6 The College has no position on the minimum number of plants to maintain specific cultivars.

Proposal C7 The College agrees with the addition of requirements to Proposal C3 to licence manufacture and pack medicinal cannabis, including the planned dose forms to be manufactured and the details of the manufacturing process to be used.

Proposal C8 The College agrees with the requirements needed to be presented with a license to sell medicinal cannabis by wholesale.

Proposal C9 The College agrees that the suppliers of unapproved non-CBD medicinal cannabis product should be licenced.

Proposal C12 The College has no position on the export of non-CBD medicinal cannabis product, other than agreeing that the export product must meet the product quality standards set under the scheme.

The concern of supply chain management will need to be considered through the process of licensing to guarantee product availability for consistent and continued care of a patient.

Distribution of products (Part D)

Proposal D The College has no position on the supply of a product via a license.

The College recommends that current proposals align with relevant cross-sector regulation for all production, manufacturing, and distribution of medicinal products to ensure safety of the patients using these products.

Prescribing (Part E)

Proposal E1 The College advocates that in the case of “on label” use of an approved product, only a specialist can prescribe.

The College does not see the need to have Ministry of Health approval for “off label” use of an approved medicinal cannabis products if, a specialist prescribes it.

The College does not agree that Ministry of Health approval is not needed for unapproved medicinal cannabis products if they meet the quality standard.

The College agrees that Ministry of Health approval should be required for unapproved medicinal cannabis products that do not meet a quality standard.

The College agrees that no change is needed in the prescribing conditions for CBD products.

Proposal E3 The College does not agree that clinical trials do not need to be applied to unapproved medicinal cannabis products.

The College recommends that the proposals have definitive and explicit wording to clarify existing sector or consumer misunderstanding of the terms doctor, medical practitioner, and specialist. Vocationally registered GPs are specialist doctors and the proposals need to apply this understanding appropriately.

For approved products, the College believes that specialists should have the prescribing authority for on-label or off-label use without Ministry of Health oversight. We view the current prescribing conditions related to CBD products (approved or unapproved) as sufficient and do not warrant any change or review.

The College position is to continue the prescribing conditions for approved or unapproved medicines, as well as on-label or off-label use regulated through the care of a specialist. This means that a medical practitioner could not prescribe without oversight of a specialist (which includes a vocationally registered general practitioner).

The College agrees that unapproved medicines that do not meet the quality standards should require Ministry of Health approval. There is insufficient evidence for the safe, therapeutic use of these products. Without full faith in the efficacy, quality or control of the product being prescribed patients risk their expectation of wellness as well as jeopardising their return to good health.

Our overall concern for medicinal cannabis efficacy is based on the lack of randomised control trials (double/triple blind) resulting in unbiased evidence bases for prescribing conditions beyond what is currently allowable. This concern is heightened by the government's lack of support for domestic clinical trials of medicinal cannabis.

The College has a long-standing opposition to any direct to consumer advertising and we strongly oppose any advertising related to medicinal cannabis. Although advertising is currently allowed under law for approved medicines, the College has reiterated its opposition to direct to consumer advertising in its Draft Therapeutics Bill submission[3] and is looking forward to the practice being made illegal.

Post Market Controls (Part F)

Proposal F The College believes all post-market controls for medicines also need to be applied to medicinal cannabis products through the enforcement powers of the Medicinal Cannabis Agency.

With the establishment of the Medicinal Cannabis Agency, the College encourages strict market controls with the belief that what we currently have as an evidence base is limited. The public perception of the performance of cannabis products does not equate to proven clinical efficacy and the role of the agency can assist in the understanding of this product by feeding back to the health sector post-market information.

The overall position

Our vocationally registered general practitioners, as part of the primary care workforce, will more than likely represent the first interaction patients will have with a specialist when discussing medicinal cannabis. We believe there is very limited data to reference when considering treatment methods and therefore medicinal cannabis should not be considered as a first line therapy. Additionally, the wording of this or any future regulations of medicinal cannabis should be clear in stating that regulations are created for the control of the product and do not represent any endorsement or create efficacy for treatment through the establishment of regulations.

The current research on efficacy and therapeutic options, as well as dosage guidance with context for New Zealand, is sparse or provided by those with vested interests. We encourage the Ministry of Health to act quickly in providing unbiased, evidenced based information specifically aimed at the health sector and not only to the consumer.

---

[3] 2019. RNZCGP. *Draft Therapeutics Bill submission*. Accessed 5 August 2019. https://oldgp16.rnzcgp.org.nz/assets/New-website/Advocacy/Submissions/Therapeutics-Bill/Submission-to-MOH-re-Draft-Therapeutic-Products-Bill.pdf

If there is government support for the growth of a local cannabis industry, then there also needs to be greater government support for randomised clinical trials allowing for greater confidence in the medicinal values of cannabis initially. The opinions that are frequently circulated through media confuse the discussion of recreational use of cannabis with the medicinal use of cannabis.

We have specifically advocated that the prescribing conditions must reside with a specialist to stem the suspected initial flood of requests for a product the health sector at large does not yet have full understanding of.

The College would like to continue engaging with the Medicinal Cannabis Advisory Group through this consultation period and will make itself available in the future for direct contact with the Medicinal Cannabis Agency.

Nāku noa, nā

Lynne Hayman
Chief Executive