

6 August 2019

Ministry of Health
PO Box 5013
Wellington 6011

By email: medicinal_cannabis@health.govt.nz

Medicinal Cannabis Scheme

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above consultation. The NZMA is New Zealand's largest medical organisation, with more than 5,000 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. Our response has been informed by feedback from our Board, Advisory Councils and members.

1. The NZMA's position on medicinal cannabis is outlined in our 2017 position statement¹ which formed the basis of our submission on the Misuse of Drugs (Medicinal Cannabis) Amendment Bill.² It is important to avoid conflating medicinal use of cannabis with recreational use of cannabis. We believe that a key principle in the approach to medicinal cannabis is ensuring it is treated the same way as other medicines. As such, a regulatory scheme for medicinal cannabis needs to appropriately address various issues including quality, safety and efficacy. We have major concerns that important aspects of the proposed regulatory scheme fall well short in this regard. We are also concerned at the seeming disconnect between the development of the regulatory scheme and the limited evidence that is currently available for medicinal cannabis. We expand on our concerns in the following paragraphs.

2. The use of credible evidence to inform and base decisions about healthcare is a core value of the NZMA. With respect to prescribing a medicine, doctors need to consider two basic principles—firstly, is the drug safe? And secondly, does it work? The safety of medicinal cannabis is yet to be established. For example, while the interaction of CBD with warfarin is already known, data on the interactions with other medicines need to be identified and published. With respect to efficacy, apart from a few indications (the rare childhood epilepsies Lennox-Gastaut syndrome and Dravet syndrome, spasticity in multiple sclerosis, and chemotherapy-induced nausea and vomiting), the credible scientific evidence for efficacy is limited. The Faculty

¹ Available from http://www.nzma.org.nz/_data/assets/pdf_file/0009/77958/Medicinal-cannabis-position-Statement-November-2017.pdf

² Available from http://www.nzma.org.nz/_data/assets/pdf_file/0012/79986/NZMA-Submission-on-Misuse-of-Drugs-Medicinal-Cannabis-Amendment-Bill.pdf

of Pain Medicine of the Australian and New Zealand College of Anaesthetists state there is no compelling evidence that medicinal cannabis is useful for chronic non-cancer pain except for multiple sclerosis-related pain.³ Recent systematic reviews and meta-analyses had similar conclusions.⁴ Given the lack of safety data from phase 1, 2 and 3 clinical trials, and the lack of evidence of efficacy for indications not stated above, there is a strong view that expecting doctors to prescribe medicinal cannabis for chronic non-cancer pain or other loosely identified medical reasons runs contrary to good medical practice and is therefore a breach of the WMA Declaration of Geneva.⁵

3. As prescribers, doctors are not comfortable prescribing any pharmaceutical, let alone medicinal cannabis, that does not meet validated, international standards of manufacture for pharmaceutical-grade medicines. If medicinal cannabis is to be available as a prescription medicine, then it must meet the same standards as other prescription medicines available in New Zealand. These include meeting Good Manufacturing Practice (GMP) as required under the Medicines Act and ensuring that all active pharmaceutical ingredients (API) meet the requirements for the New Zealand Product Quality Standards Monograph. Other than potentially reduced costs of production, it is difficult to envisage any benefits of using lower standards such as Good Production Practice (GPP) over GMP.

4. It is essential for prescribers to have access to a comprehensive product monograph including data on safety and drug interactions. To improve the evidence base, we suggest the Ministry consider supporting the development of high-quality clinical trials for the use of medicinal cannabis. Particular consideration needs to be given to collecting safety data. Relying on the Centre for Adverse Reactions Monitoring (CARM) for this purpose is unlikely to be sufficient given the combination of the relative lack of evidence regarding the adverse events of medicinal cannabis products compared with other more commonly prescribed medications, and the fact that at best, only about one in ten adverse reactions are reported to CARM.⁶

5. Without knowing more details about what products might be available under the new scheme, it is difficult to respond to questions about dose form requirements or whether there should be a limit on the amount of THC or CBD in these products. Nevertheless, we agree that food products containing medicinal cannabis should not be allowed under the scheme (unless specifically approved under the Medicines Act), primarily because of difficulty with dose titration of edibles.⁷ We also believe that smoking should not be a route of administration for medicinal cannabis in view of concerns about the harms of this route of administration.

6. With respect to proposed prescribing requirements, we agree that it is reasonable to differentiate between CBD products and THC products. While we are comfortable for CBD products to be prescribed by any medical practitioner or nurse practitioner (our concerns around limited safety and efficacy data notwithstanding), we believe it is important to retain the requirements for specialist sign-off for approved THC-products that are used either on- or off-label. We note that the definition of a specialist that is proposed includes a specialist

³ Medicinal cannabis – no silver bullet. 12 July, 2019. Available from

<http://www.anzca.edu.au/communications/media/media-releases-2019/medicinal-cannabis-no-silver-bullet>

⁴ Whiting PF, et al. Cannabinoids for Medical Use: A Systematic Review and Meta-analysis. JAMA. 2015 Jun 23-30;313(24):2456-73; Stockings E, et al. Cannabis and cannabinoids for the treatment of people with chronic noncancer pain conditions: a systematic review and meta-analysis of controlled and observational studies. Pain. 2018 Oct;159(10):1932-1954

⁵ Available from <https://www.wma.net/policies-post/wma-declaration-of-geneva/>

⁶ BPAC. Adverse reaction reporting tool. BPJ. 2009. Available from https://bpac.org.nz/BPJ/2009/June/docs/bpj21_adversereaction_pages_50-52.pdf

⁷ Vandrey R, et al. Cannabinoid Dose and Label Accuracy in Edible Medical Cannabis Products. JAMA. 2015 Jun 23-30;313(24):2491-3

(vocationally registered) General Practitioner. In addition, there is strong (but not unanimous) support for a requirement to further specify that only certain types of specialist can sign-off on approved THC-containing products (eg, pain specialist, oncologist, neurologist, paediatric neurologist, palliative care specialist). Such a requirement would be an important protection against drug-seeking behaviour and diversion onto the black market. It is appropriate to draw lessons from opiate use where 90% of opiates available on the black market in New Zealand have been diverted from prescriptions.

7. We understand that most of the medicinal cannabis products expected to be covered by these regulations will be licensed as unapproved medicines (reflecting the lack of sufficient data on safety and efficacy). We believe that licensing such products is inconsistent with the primary purpose of medicines regulation which is to keep people safe. For example, the Medsafe website states that: *“The purpose of medicines legislation is to manage the risk of avoidable harm associated with the use of medicines by ensuring that: i) medicines meet acceptable standards of safety, quality and efficacy”*. The recent consultation on the Therapeutic Products Bill stated that *“the intention under the Therapeutic Products Bill is to try to minimise the use of unapproved medicines in New Zealand”*. It is of concern that an expected outcome of the medicinal cannabis scheme runs directly counter to the objectives of the new Therapeutic Products Bill.

8. There is a lack of clarity on how various controls under the Medicines Act (and its replacement) will be exercised if licenses for medicinal cannabis are issued under the Misuse of Drugs Act as is being proposed. We would be concerned if Medsafe rules and some existing controls under the Medicines Act are sidestepped for medicinal cannabis. Particular areas that we seek clarification on relate to the following: enforcement provisions (these are being strengthened under the Therapeutic Products Bill); pharmacovigilance (monitoring adverse reactions, complaints and investigations, product recalls), responsible person (will this person be legally responsible in the same way as the sponsor is under the Medicines Act? Will the other expectations of sponsors set down by Medsafe apply?).

9. By being involved in supporting the growth of the medicinal cannabis industry, we are concerned that the regulator is extending its remit beyond what it should have been mandated to do. The primary purpose of existing medicines regulation—both the Misuse of Drugs Act and the Medicines Act—is about public safety, not about access to cheaper products or ensuring a thriving domestic industry. In the same way, it would be inappropriate to manipulate standards under the Health Practitioners Competence Assurance Act to meet labour market needs in the health workforce.

10. We have concerns relating to the medicolegal implications that may arise as a result of the proposed scheme. As most medicinal cannabis products are expected to be unapproved medicines, conventional data sheets will not be available and therefore there will be little guidance for prescribers. Prescribing of unapproved medicines should only be in rare cases but as a result of this scheme, could be a more common occurrence adding compliance and risk dimensions. The Ministry has conveyed that “it will be up to the prescriber to decide effectiveness for any indication”. We note the existing advice on Medsafe’s website regarding responsibility under the HDC Code of Rights when prescribing unapproved medicines.⁸ We seek clarification as to whether prescribers’ obligations under the HDC Code as they have been interpreted for the prescription of unapproved medicines will apply for medicinal cannabis, given these products are to be regulated through a different pathway to other medicines. We are in the process of seeking advice on whether a prescriber could be medico-legally liable if it is

⁸ <https://www.medsafe.govt.nz/profs/PUArticles/December2013UnapprovedMedicinesAndCodeOfRights.htm>; <https://www.medsafe.govt.nz/profs/RIss/unapp.asp>

subsequently discovered (perhaps years later) that an unapproved medicinal cannabis product has caused harm.

11. Given the lack of evidence around safety and efficacy as well as the potential for drug seeking behaviour and diversion, we wish to flag the possibility that some practitioners / practices may opt to not prescribe medicinal cannabis altogether (with perhaps a notice in their waiting room conveying this). It is also likely that patients could end up shopping around to find willing prescribers, thus further fragmenting care and leading to a scenario where there are known medicinal cannabis prescribing hubs or practitioners.

12. In view of the currently limited data on efficacy and safety, including drug interactions, we ask the Ministry of Health to develop and maintain a website containing phase 3 trial data and reports of significant drug interactions. Such a resource would be helpful for medical practitioners to share with patients in view of the very significant public pressure that there will be to prescribe medicinal cannabis.

13. Finally, we believe it is important to consider measures to mitigate against the risks of people driving while using THC-containing medicinal cannabis products. This should include requirements for warning labels on the packaging.

We hope our feedback is helpful and look forward to receiving clarification on the issues we have raised. We would also welcome the opportunity for further engagement with the Ministry as it progresses this work.

Yours sincerely

A handwritten signature in blue ink that reads "K. Baddock". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Dr Kate Baddock
NZMA Chair