

**Medicinal Cannabis Advisory Group Meeting Minutes**

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| **Date:**  | Monday 29 April 2019 |
| **Time:** | 9.30am–4.00pm |
| **Location:** | Bunker Room, Miramar Links, 1 Stewart Duff Drive, Wellington |
| **Chair:** | Dr Russell Wills |
| **Attendees:** | Committee – Dr Brian Ensor, Judy Leader, Professor Michelle Glass, Dr David Burrell, Rebecca Reider, Manu Caddie, Kali Mercier, Tara Creaven-Capasso, Simon RoyalSecretariat – Andrea Eng, Kayla Cook, Cherish Low, Valerie Mills, Susan ThomsonMinistry of Health – Chris James, Jane Hubbard, Sharon Woollaston |
| **Apologies:** | Dr Andrew Butler, Dr Cynthia Sharpe, Simon Royal, Suzy Barber |

| **Item** | **Notes** |
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| **1** | **Tea and coffee on arrival 9.00am–9.30am**  |
| **2** | **Mihi whakatau, karakia timatanga, whakawhānaungatanga**The Chair welcomed everyone to the meeting. |
| **3** | **Declaration of conflicts of interest**No material conflicts of interest were declared. |
| **4** | **Break for Morning Tea 10.00am–10.15am** |
| **5** | **Agenda**The Medicinal Cannabis Advisory Group (the Advisory Group) discussed and agreed the values and behaviours that would guide its discussions. The Advisory Group highlighted the importance of equity considerations as well as Treaty of Waitangi obligations and pointed out that this should be at the forefront when considering options or giving any advice on the Medicinal Cannabis Scheme.The Advisory Group agreed to the key points of discussion in the agenda, as outlined in these meeting minutes.The Advisory Group discussed the timeline and asked whether there would be another opportunity to provide input into the Medicinal Cannabis Regulatory Scheme Consultation Document (the Consultation Document) before it goes to Cabinet for approval. The Secretariat advised that another teleconference would be arranged to allow input on any changes from the Advisory Group following the meeting. |
| **6** | **Terms of Reference**All Advisory Group members agreed to their obligations as set out by the Terms of Reference. |
| **7** | **MCAG Handbook**The Advisory Group acknowledged that members who are also public servants are not entitled to be paid fees for Advisory Group business if this is conducted during regular paid work time (in accordance with the Local Government Act 2005).**Action:** Secretariat to organise two further meetings; an Advisory Group teleconference (for the week of 13 May) and the next face to face Advisory Group meeting after public consultation (around 19 August). |
| **8** | **Background and Overview of Scheme and Regulatory Proposals**The Secretariat gave a brief overview of the background of the Medicinal Cannabis Scheme and the development of the Consultation Document.In 2017, as part of the Government’s 100 day plan, Cabinet agreed to introduce legislation to improve access to medicinal cannabis products. The Misuse of Drugs (Medicinal Cannabis) Amendment Act 2018 came into effect on 18 December 2018 and, among other things, provided for regulations to be made to prescribe standards for all stages of cultivation, production and manufacture, and for medicinal cannabis products. These regulations are required to be made no later than 18 December 2019. The Medicinal Cannabis Scheme aims to improve access to products by increasing supply through enabling domestic cultivation of cannabis and manufacture of quality medicinal cannabis products, and facilitating patient access to products. |
|  | **Break for lunch 12.00pm–1.30pm** |
| **9** | **Proposed Quality Standards**The Secretariat presented the proposals for quality standards: **Quality standards for cultivation: three approaches for consideration*** Cultivators must meet the manufacturer’s quality standards.
* Cultivators must follow the cultivation process standard set by the regulator.
* Cultivators must meet the product quality standard for starting material set by the regulator.

It was noted that the medicinal cannabis industry may prefer the option of having Good Agricultural Practices (GAP) or Good Agricultural and Collection Practices (GACP) requirements to provide quality assurance for the starting material.The Advisory Group noted that there was a lot of information in the Consultation Document which made the details of the three approaches hard to follow and suggested the information could be better presented in the form of a table.The Advisory Group noted that it was unclear as to the testing requirements that the Medicinal Cannabis Agency (the Agency) may require.It was suggested that the proposals for cultivation quality standards should be presented as options for consultation.**Action:** Secretariat to consider presenting the information on the three options for the cultivation quality standard in a table format. **Action:** Secretariat to clarify in the Consultation Document what may be tested and why. |
| **10** | **Quality Standards for Manufacturing**The Secretariat advised that there was no universally accepted standard for the manufacture of medicinal cannabis products. Two approaches were looked at by the Ministry: * The current New Zealand and internationally recognised quality manufacturing standard followed by medicines manufacturers – Good Manufacturing Practices (GMP).
* The Canadian framework for non-prescription health products containing cannabis – Good Production Practices (GPP).

It was noted that some medicinal cannabis industry stakeholders have expressed a preference for GPP (a lower quality standard when compared to GMP) as the manufacturing quality standard. It was also noted that for those NZ industry stakeholders looking to export NZ medicinal cannabis products, as part of their commercial strategy, they are currently designing their facilities and quality management systems to comply with GMPs as the manufacturing quality standard, even if GPP becomes the NZ standard. It was also noted that if New Zealand had two regulatory frameworks, it would be challenging for the government to administer, specifically having one framework for medicinal cannabis products (e.g. GPP) and the other being GMP for all other medicines.The Advisory Group discussed the risks and benefits of manufacturing to GMP compared with GPP in terms of the cost and time required to get product to market, the cost of products, patient access and health outcomes and the minimum quality standards necessary for these products.It was noted that currently some New Zealanders are using illicit cannabis or unapproved medicinal cannabis products which have been produced with little or no quality standards. The Secretariat noted that there was no information publicly available comparing setup and operational costs for GPP versus GMP. The Advisory Group requested the Consultation Document include more information on the differences between GMP and GPP. Allowing patients to grow their own cannabis was suggested as an option to improve legal access. However, some members of the Advisory Group were opposed to this, citing that patients are not permitted to grow their own medicines.**Action:** Secretariat asked to look for more information on comparing patient health outcomes of products manufactured under GMP vs products manufactured under GPP. **Action:** Secretariat asked to include information on the set up time and costs as well as operational costs of GMP vs GPP in the Consultation Document if possible.**Action:** Secretariat to consider including an evidence based assessment of the risks and benefits of using cannabis in the Consultation Document. |
| **11** | **Prescribing Requirements**At this meeting, some members of the Advisory Group noted that in terms of patient safety, prescriptions should be written by an authorised prescriber and dispensed from a pharmacy. Some other members did not agree with this approach and wanted an investigation of other options such as direct to consumer online sales. It was noted that in Canada patients can get health products containing cannabis directly from the producer or an online pharmacist, which reduces the cost but misses the opportunity for a discussion with the pharmacist.Some members of the Advisory Group noted that prescribed medicinal cannabis products should be treated in the same manner as any other medicine and acknowledged that there are prescribers other than medical practitioners. A point was raised regarding the use of the word “doctor” rather than authorised prescriber with regard to prescribing unapproved medicines. It was noted by the Secretariat that most of the medicines that will be under the Scheme will be unapproved medicines, and that under current legislation, only medical practitioners would be able to prescribe them.There was discussion around prescribing requirements. Some members of the Advisory Group were interested in the prescribing requirements and restrictions for other controlled drugs (Special Authority system and Controlled Drug prescriptions). Specialist oversight for prescribing was discussed, including what qualifies one as a specialist; specialist initiation, prescription and endorsement; different access to specialists across DHBs and peer review for the prescribing decision. It was noted by some Advisory Group members that restrictions on prescribing should be proportional to risk. It was noted by some Advisory Group members that the risks for prescribing to children are higher than the risks for adults. It was suggested by some members of the Advisory Group that there is already pressure to prescribe certain medications and that some doctors would like medicinal cannabis prescriptions to also require a specialist recommendation for additional assurance. However it was also noted that the requirements for specialist approval may pose a barrier to access.Some members of the Advisory Group noted that the draft consultation document mentioned that there were risks associated with the use of medicinal cannabis but did not mention what these risks were. It was noted that information on the inherent risks of the use of medicinal cannabis products should be included in the consultation paper.The question was raised of whether cannabidiol could be made to be an over the counter medication rather than a prescription medicine. The Secretariat explained that this falls within the scope of the Medicines Classification Committee, and that anyone is allowed to apply to that committee for a reclassification.There was a discussion of prescribing and dosages. Specifically there was a question raised of whether doctors must prescribe fixed dosages and cannabinoid ratios, given that working out the proper dosing tends to take some trial and error by the patient using different strains of cannabis. It was noted that in the Canadian system, patients could go to a doctor for a medical document which allows patients to access health products containing cannabis.**Action:** Secretariat to consider clarifying how patients will obtain medicinal cannabis prescriptions and if it differs from the current method.**Action:** Secretariat toconsider inserting a footnote in the consultation document that at the moment, only medical practitioners can prescribe unapproved medicines, although this may change in the future. |
| **12** | **Prescriber Information Needs**Members discussed options to increase knowledge and awareness of medicinal cannabis products within the health care sector. Members acknowledged a need for prescriber education regarding medicinal cannabis products within a New Zealand context, including in terms of Treaty obligations.The question was raised as to whether the field of cannabinoid medicine could become recognised as its own medical specialty, in order to allow doctors with knowledge in this area to prescribe medicinal cannabis products. It was noted that a medical sub-specialty typically emerges over time, initiated by an association of doctors.**Action:** Secretariat to advise group on prescriber education options within New Zealand, how information can be disseminated, and increasing avenues for education (how to make it as widely available as possible). |
| **13** | **Fees and Charges**The Advisory Group raised a concern that the groups who currently experience the worst health outcomes (Māori, Pacific peoples, the poor and children) may not benefit from the establishment of the Medicinal Cannabis Scheme. The issue of the price of medicinal cannabis products was raised as there is already marked variability in mark-ups by pharmacies of unfunded and over-the-counter medicines, which increases costs to patients. A discussion occurred around funding options which should be included in a paper to go to the Minister of Health.The goal of minimising patient’s reliance on the illicit market was agreed to as a goal of the scheme in order to maximise positive health outcomes. It was noted that this will require balancing product affordability with quality. A question was raised whether some alternative funding pathway (outside of PHARMAC) could be implemented to reduce the cost of medicinal cannabis products.**Action:** Secretariat to amend document to acknowledge the need for equity of access and seek consultation feedback on barriers to access. |
|  | **Break for Afternoon Tea 3.00pm–3.15pm** |
| **14** | **Future Meetings**The next meeting will be a teleconference held during the week beginning 13 May 2019. Time and exact date TBC. |
| **15** | **Karakia whakamutanga**  |

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The meeting closed at 4.00pm