

**Medicinal Cannabis Advisory Group Meeting Minutes**

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| **Date:** | Wednesday 4 September 2019 |
| **Time:** | 9.30am–4.00pm |
| **Location:** | Brentwood Hotel, 16 Kemp Street, Wellington |
| **Chair:** | Dr Russell Wills |
| **Attendees:** | Committee – Dr Brian Ensor, Judy Leader, Professor Michelle Glass, Dr David Burrell, Manu Caddie, Kali Mercier, Tara Creaven-Capasso, Dr Andrew Butler, Suzy Barber, Simon Royal, Rebecca Reider (by videoconference)  Secretariat – Andrea Eng, Kayla Cook, Cherish Low, Valerie Mills, Susan Thomson  Ministry of Health – Chris James, Jane Hubbard, Sharon Woollaston, Emma Hindson, Leonard Hewa |
| **Apologies:** | Dr Cynthia Sharpe |

| **Item** | **Notes** |
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|  | **Meeting commenced 9.40am** |
|  | **Overview of Medicinal Cannabis Scheme Proposals**  The Secretariat gave a brief overview of the Medicinal Cannabis Scheme Proposals (the Proposals) outlining: quality standards for cultivation, manufacture, API, and finished products, licencing requirements, the interface between medicinal cannabis and industrial hemp, small scale vs. large scale licences, limits on declaring seed, limits on transfer between researchers, licence conditions, prescribing requirements, and fees.  The Medicinal Cannabis Advisory Group (the Advisory Group) noted that they would like to continue discussion during this meeting regarding three policy issues: funding, equity, and education for prescribers. |
|  | **Morning tea break 10.50am–11.00am** |
|  | The Secretariat presented the proposals for quality standards:  **Quality standards for cultivation**  The Advisory Group noted that there was a strong preference in the Medicinal Scheme Consultation (the Consultation) feedback in support of the cultivator meeting the manufacturer’s quality standard.  A question was raised as to what the limits on pesticides would be. The Secretariat advised that they were currently working with both the Ministry for Primary Industries (MPI) and the Institute of Environmental Science and Research (ESR) to develop a New Zealand specific pesticide standard.  **Quality standards for manufacturing**  The Advisory Group discussed the feedback from the Consultation on the quality standard for manufacturing. In general, feedback from industry stakeholders indicated a preference for the Good Manufacturing Practice (GMP) standard. Consumers/patients indicated a strong preference for a combination of GMP and a New Zealand specific Good Production Practices (GPP) standard, while medical practitioners strongly indicated that medicinal cannabis products should only be manufactured to GMP.  It was noted that although everyone’s feedback is important, medical practitioners would be prescribing medicinal cannabis products. Consultation feedback suggested they are highly unlikely to prescribe products that are not manufactured to GMP, and the objective of increasing access to products would not be met.  The Advisory Group and the Secretariat discussed the reasons why Health Canada decided to opt for GPP as their manufacturing standard, and the differences between the regulatory environments in Canada compared with New Zealand.  The Advisory Group acknowledged why GMP would be the preferred manufacturing standard by stakeholders, but some Advisory Group members noted that The Ministry of Health (the Ministry) should consider an interim measure, such as permitting personal cultivation ”grow your own”, to enable quicker access to products whilst manufacturers were preparing and manufacturing products to the GMP standard.  Timelines as to how long it would realistically take medicinal cannabis products that were manufactured to GMP to get to market were discussed, with one member of the Advisory Group suggesting that it could be as soon as the middle of 2020. The Secretariat highlighted that it took Australia 2 and a half years to get medicinal cannabis products to market. The Secretariat is currently discussing with Australia the reasons behind why it took so long, as well as steps that the Ministry could put in place to ensure that it does not take as long in New Zealand.  **Quality standards for Active Pharmaceutical Ingredients (APIs) and finished products**  The Advisory Group discussed what dose forms would be permitted under the Scheme and in particular, what dose forms could be exported to other countries.  Some members of the Advisory Group expressed concerns about permitting vaporisation of medicinal cannabis products. Other members noted that vaporising dry herb (via a vaporiser) is a relatively standardised way of administering medications to patients. Discussion took place around the devices that could be used to administer the vaporisation of dry medicinal cannabis herb and how these could be regulated.  **Action:** Secretariat to clarify what is meant by vaporising medicinal cannabis products and what form of vaporisation is proposed to be permitted under the Scheme. |
|  | **Licence to Cultivate**  The Advisory Group discussed the requirement for licence holders, directors, and partners to have no convictions against the Misuse of Drugs Act 1975 or any other drug-related offence. The Advisory Group also discussed convictions involving dishonesty under the Crimes Act 1961 and the barriers this may pose.  The Secretariat advised that people with drug convictions could apply for a licence, but the granting of a licence is at the Minister’s discretion. The Secretariat agreed to look into the application of the Ministers discretion to people convicted of a crime involving dishonesty within the meaning of the Crimes Act 1961 in order to prevent any inequities this requirement may cause.  Questions were raised as to what the Minister took into account when looking at allowing an exemption. The Secretariat stated that an exemption had not been considered before.  The Advisory Group further noted that there should be other means by which inequities could be addressed in relation to conviction requirements for those that don’t meet them and a two year imprisonment threshold for licence holders, directors and partners should be looked into.  **Tetrahydrocannabinol (THC) requirements**  Some members of the Advisory Group mentioned that they would like the limit for THC to be raised from 0.35 percent to one percent.  The Secretariat advised that the 0.35 percent limit was consistent with how industrial hemp is regulated. If this limit was increased then the Ministry would need to change legislation as well as develop and implement testing to ensure that the THC level is under one percent.  **Interface between the industrial hemp regime and the medicinal cannabis regime**  The Advisory Group asked for the rationale behind the proposal to limit the number of industrial hemp seeds that could be transferred to the Scheme to 50 seeds or 20 seedlings.  The Secretariat advised that this limit was to make sure no one was unfairly disadvantaged and ensure that there was a level playing field for all people wanting to enter the medicinal cannabis industry. Seed transfer limits throughout the Scheme have been kept uniform for consistency.  Some members of the Advisory Group argued that giving some people or companies an advantage would be a good thing as products will end up on the market faster.  **Licences for small scale versus large scale cultivation**  The Advisory Group questioned why a 200 square metre limit was identified as the threshold between small-scale and large-scale cultivation.  The Secretariat advised that distinguishing between large and small cultivators was based on a risk proportionate approach, and subject to different licencing fees accordingly. It was highlighted that a third of respondents from the Consultation identified that they would be cultivating an area of under 200 square metres.  Some members of the Advisory Group questioned the economic viability of having a 200 square metre threshold but identified that this may not be relevant for all applicants as it would depend on their intent when applying for a licence under the Scheme. |
|  | **Break for lunch 12.00pm–12.30pm** |
|  | **Security Requirements**  Members of the Advisory Group noted that they would like the security requirements for low THC and high THC crops explained.  The Secretariat stated that for high THC crops, it is important to prevent access to the crop by unauthorised people, but further work needed to be done in this area. The Secretariat also advised that work was underway to develop guidance, application forms and workshops to facilitate industry and Māori with the application process.  **Action:** Secretariat to do more work into the differing security requirements for a high THC crop versus a low THC crop.  **Declaration of illicit New Zealand seed**  Some members of the Advisory Group questioned why there was a proposed limit on the number of seeds being declared at any one time and not a limit on the number of declarations, considering that it is not intended to be an ongoing source of supply from the illicit market.  Discussion occurred around the varying times that cultivators may enter the medicinal cannabis industry or set up and declare illicit seeds. Concerns were raised around having any time limits on declarations or allowing illicit growers to be taken advantage of.  **Transition of plants from current cultivation licences**  Some members of the Advisory Group argued that a limit of 50 seeds or 20 seedlings for the transfer of genetic material from the current Licence to Cultivate to the Scheme would be a barrier, as the bulk of research would have to be destroyed. It was suggested by some members that the Scheme should allow those who currently have a Licence to Cultivate to be able to continue breeding and transfer all of their material over to the Scheme. The Secretariat advised that this would be a breach of the current licence purpose which is for research, and not for preparing to grow medicinal cannabis for a commercial purpose, as stipulated under the United Nations Single Convention on Narcotic Drugs 1961.  Discussion took place around how those who are currently undertaking medicinal cannabis research could be able to continue this activity whilst also having a commercial licence and how this could be enforced.  **Licence to Manufacture**  Some members of the Advisory Group questioned why the Licence to Manufacture under the Scheme will be issued for only one year, stating that this may pose a barrier to some companies/investors who are wishing to enter the medicinal cannabis industry. The Secretariat advised that this was consistent with all of the other licences that are currently issued, and if the licences were increased to two years then the fees would also increase, which may pose additional economic barriers for some companies wanting to enter the industry.  Discussion took place around what would be required to renew a licence under the Scheme, comparing this to what is currently done in Canada and what economic barriers to access this may cause. The Secretariat acknowledged that the current fees had not been modelled on likely financial return and that more work will go into this.  **Action:** Secretariat to look into fees and the barriers one year licences may have.  **Unapproved medicinal cannabis products under the Misuse of Drugs Act**  Discussion took place around who would be able to prescribe unapproved medicinal cannabis products. The Secretariat advised that due to the Medicines Act 1981, only medical practitioners would be able to prescribe these, but this may change when the Therapeutic Products Bill comes into force.  Some members of the Advisory Group raised concerns about the equity issues this may cause, especially for those prescribers who are in low decile and/or rural areas, stating that the Ministry should include this as part of their education to prescribers and consumers as most may not be familiar with the prescribing restrictions in place due to current legislation. |
|  | **Prescribing of unapproved medicinal cannabis products that are controlled drugs that don’t meet the quality standards**  Discussion occurred about what a specialist is and how this applied against the Good Prescribing Practices issues by the Medical Council.  **Prescribing of unapproved medicinal cannabis products that meet the quality standards**  Discussion occurred around the requirement to remove specialist approval for unapproved medicinal cannabis products that meet the quality standards. Some Advisory Group members expressed concern over removing specialist requirements and what this would mean for general practitioners, while other Advisory Group members disagreed stating that it is a barrier and feedback from the Consultation was nearly uniformly in favour of removing this requirement.  A concern was raised by some members of the Advisory Group that some of the proposals of the Scheme may not align with the New Zealand Medical Council’s Good Prescribing Practices. According to these, medicinal cannabis products may not be able to be prescribed by general practitioners, as they may not fall into their scope of practice to prescribe.  Some members of the Advisory Group thought that the Ministry should consider incorporating the Medical Council’s definition of scope of practice into the cabinet paper so that it is aligned.  The proposal to allow all medical practitioners to prescribe approved and unapproved medicinal cannabis products that meet the quality standards, except for where the products are being prescribed for paediatric patients, was highlighted. Some Advisory Group members raised a point as to whether or not this would be required for other vulnerable populations such as geriatric patients. |
|  | **Education**  Discussion took place around the implementation of reliable and credible education information to prescribers, industry, and consumers.  The Advisory Group supported the idea of an education programme to be written with the input of senior practitioners, industry and consumers to ensure balance. The Advisory Group noted education is an important and necessary aspect of the Scheme.  Some members raised the concern that the majority of products under the Scheme will be unapproved and therefore will not be able to be advertised to prescribers. Discussion took place as to how prescribers can be informed of these products in order to increase access to patients without undermining existing legislation.  Some members of the Advisory Group highlighted that the Therapeutic Goods Administration (TGA) have published medicinal cannabis guidance documents for prescribers to give them dosing information.  Legislation requirements around refrigerated controlled drugs were discussed, noting that there is a current exemption for a medicinal cannabis product, Sativex.  **Action:** Secretariat to look into how prescribers can be made aware of the products that are available under the Scheme. |
|  | **Break for Afternoon Tea 3.00pm–3.10pm** |
|  | **Feedback on key issues**  Some members of the Advisory Group suggested that there could be a five year review incorporated into the regulations in order to monitor the progress of the Scheme as well as ensure public confidence.  **Equity**  The Advisory Group noted that they would like an update from the Secretariat as to the work they were doing to address any potential equity issues that the Scheme may cause. The Secretariat advised that they have had conversations regarding the development of a Māori specific workshop as well as conversations with the Deputy Director-General of Māori Health in order to address the Te Tiriti o Waitangi issues regarding participation and partnership.  **Finished product costs**  Discussion occurred around the overriding equity issue that high mark-ups from pharmacies are likely to be a barrier for patients who are prescribed medicinal cannabis products. Some members disagreed with this, stating that more pharmacies don’t put much of a mark-up on expensive medicines as pharmacists recognise that most patients can’t afford these and market will likely manage most of the varying costs of medicines.  **Post market surveillance**  Some members of the Advisory Group supported the notion to include post-market surveillance as part of the education programme. |
|  | **Next Steps**  The Secretariat will include feedback from the Advisory Group and the Consultation into a Cabinet paper to go to the Minister of Health. |

Meeting closed 4.20 pm