**Minutes** 

**Expert Advisory Committee on Drugs meeting**

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| **Date:** | Wednesday 27 April 2016 |
| **Time:** | 10am - 3pm |
| **Location:** | The Viscount Room, Wellington Airport Conference Centre, Level 2, Main Terminal Building, Wellington International Airport |
| **Chair:** | Associate Professor Cynthia Darlington |
| **Attendees:** | Committee – Associate Professor Cynthia Darlington (Chair), Hannah Partington (on behalf of Dr Keith Bedford), Detective Superintendent Gregory Williams, Richard Schmidt, Lynette Knox, Dr Stewart Jessamine, Jamie Bamford, Dr Vicki Macfarlane  Observers – Sharon Woollaston, Sue Scott  Secretariat – Alison Cossar, Vidhiya Damodaran, Fraser Colson, Cherish Low (minutes) |
| **Apologies:** | Dr Jaki Horn, Dr Keith Bedford, Haley Ataera |

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| **Item** | **Notes** |
| 1 | **Morning tea on arrival 9.45am – 10am** |
| 2 | **Welcome, Introductions and apologies**  The Chair welcomed everyone to the meeting and introductions were given for all attendees.  Apologies were received for Dr Keith Bedford and Dr Jaki Horn. Hannah Partington from ESR attended on behalf of Dr Keith Bedford to speak about notes provided for item 5.  It was also noted that [redacted] has resigned as a member of the Committee as the community medicines representative, as she has relinquished her medical licence and can no longer sit on the Committee. |
| 3 | **Conflicts of interest**  Associate Professor Cynthia Darlington declared a conflict of interest and asked Dr Stewart Jessamine to Chair the meeting during the Cannibidiol discussion as she has been involved in preclinical research into cannabinoid pharmacology.  No other conflicts of interest were declared. |
| 4 | **Previous minutes – Action points and standing points**   1. [redacted] gave an update regarding the proposed working group on prescribing practise. The status of this work is currently at a researching and collaborating stage with the relevant people. Potential information sources include the NZ ePrescription service, PHARMAC/Pharms data and the Opioid Overdose Advisory Group as part of the NZ Drug Foundation. 2. An update was also given on tramadol annual oversupply data and effects observed on tramadol and other pain medications following a MOH warning on prescribing oxycodone. It was unclear when the warning on prescribing oxycodone was given and the information has been provided side by side over a period in which the warning was likely given (2008 – 2015). 3. An update on section 29 data for zolpidem was provided via hand-outs. Regarding the scheduling of both zolipidem and zopiclone as Class C5 controlled drugs under MoDA, feedback had been received from industry which was mainly supportive of the proposal. The one manufacturer who did not support the proposal sited cost issues as their main reasoning. The health report and letter to the Minister have been drafted and are waiting to be finalised. 4. [redacted] gave an update regarding the WHO Expert Committee on Drug Dependence. Reviews are carried out on certain substances that raise concerns, which are then determined if scheduling under either the Single Convention on Narcotic Drugs (1961) or the UN Convention on Psychotropic Substances (1971) is necessary. Recommendations are then taken to the Commission on Narcotic Drugs through the UN which are then ratified. This happens several times a year. Seven substances were scheduled at the 37th meeting held in December 2015 which include 4,4-DMAR, PMMA, acetylfentanyl, MT-45 alpha-PVP, MXE, phenazepam. Since signing these conventions, the Committee have an obligation to have a look at these substances at some point, taking into account the current work load of the Secretariat. Alpha-PVP had been put forward for this meeting as it is already present in NZ whereas the others are not as prevalent. 5. [redacted] gave a brief update regarding his inclusion on the Inter Agency Committee on Drugs (IACD). Currently, the main priority for the IACD was looking at the implementation of the National Drug Plan as a core governance role. It was noted that more interaction between the IACD and EACD is needed as there is an overlap between the two Committees’ functions and working more closely would be beneficial.   **Action:** Secretariat to liaise with IACD Secretariat regarding lines of communication with respect to emerging substances for the EACD to  consider.   1. The Chair asked that the Committee put forward any suggestions for replacements for [redacted] as community medicine representative.   **Action:** [redacted] will speak to some General Practitioners that have expertise in addiction and work closely with police.  **Action:** Secretariat to go to The Royal New Zealand College of General Practitioners, and the Pharmacology and Therapeutics Advisory Committee (PTAC) to ask for nominations. |
| 5 | **Cannabidiol (CBD)**  [redacted] (Senior Policy Analyst, MoH) and [redacted] (Principal Advisor, Medicines control) attended the meeting at 10.21am.  Dr Stewart Jessamine chaired the discussion as Assoc. Prof. Cynthia Darlington had declared a conflict of interest due to her involvement in preclinical research into cannabinoid pharmacology. The Committee had no issues with Assoc. Prof. Cynthia Darlington being present for the discussion given her expertise in the area but she would be excluded from the decision making process due to the outcome potentially impacting the regulatory environment for research.  [redacted] gave a brief contextual overview within the Ministry of Health (MoH). [redacted] has been involved in therapeutic uses of controlled drugs for the last few years, with her main area of interest recently being around medicinal cannabis. The MoH policy unit are of the understanding that Minister Dunne is comfortable around the current legal framework regarding access and use of controlled drugs, but he is interested to see if the policies and processes are as streamlined as they can be regarding patient safety and access.  The policy unit are currently doing work around medicinal cannabis classification in line with the EACD meetings consideration. [redacted] gave a brief overview of the function of Medicines Control. Medicines Control is a regulatory unit that regulate the medicines supply chain, which includes controlled drugs. The classification of medicinal cannabis has been quite topical in the last year and whatever final recommendations are made by the Committee will affect Medicines Control as they administer licences, approvals, permissions etc.  [redacted] advised that currently, if a practitioner wishes to prescribe a cannabinoid or products that contain cannabinoids, they have to make an application to the Minister. Currently there are no products containing only CBD that are approved medicines both domestically and internationally. There are however, a number of non-pharmaceutical products available. It was noted that there was a difference of opinion between ESR and MoH regarding whether or not CBD should be considered a controlled drug or not. The Therapeutic Goods Administration (TGA) in Australia have recently down-scheduled CBD to a prescription only medicine with less than two percent of other cannabinoids as most CBD extracts contain small amounts of tetrahydrocannabinol (THC) due to the difficulty and associated cost to separate the two substances. The Misuse of Drugs Act (MoDA) only requires one molecule of a controlled substance to be present in a preparation for it to be captured as a controlled drug.  There is an entry in the Medicines Regulations for CBD as a prescription medicine, however, if it is also considered a controlled drug, then MoDA acts as the dominant piece of legislation.  The technical paper looked at the potential therapeutic effects of CBD in comparison to the abuse potential. The Committee had been asked to determine whether or not there was sufficient evidence to make a recommendation for de-scheduling CBD from being captured under MoDA so that it is classified as a prescription medicine only. The Committee was also asked to consider an amendment allowing CBD preparations to contatin THC and other cannabinoids found in cannabis up to a certain threshold to enable the de-scheduling of CBD to take effect. The Committee considered the options for streamlining medical access to CBD as a controlled drug.  [redacted] advised that there were some controlled drugs that had been exempted from the ministerial approval requirements process as they had been specifically named as exempt as medicines under the Misuse of Drugs Regulations. Blanket or general approvals, permissible under Regulation 22 of the Misuse of Drugs Regulations, have also been issued to supply prescribe and administer certain controlled substances . There are multiple avenues that could be considered with regard to what mechanisms are available to streamline the process to access CBD based medicines, however, the main driver for the reclassification of CBD is the TGA decision because they have set a new approach to cannabinoid based medicines.  [redacted] spoke to the notes submitted by [redacted] which covered a few issues with the current legislation. [redacted] also advised that although CBD does have the same molecular formula, ESR do not consider CBD as an isomer of THC within the specific chemical designation under MoDA as CBD is significantly different in structure from THC and is not explicitly named under the legislation. ESR also do a lot of testing for hemp growers who have expressed interest in information regarding CBD content of hemp plants and hemp fibre for therapeutic use. Another point of consideration is that more clarification around what is considered the definition of medicinal cannabis is needed.  Research in this area can be difficult due to the bureaucratic layers to obtain permission. Moving CBD out of MoDA would remove those controls but would still need to address the THC component of the argument as THC is specifically named as a controlled drug under MoDA. More research is required regarding the potential associated risks, however, the risk of CBD causing psychoactive harm is very low as CBD on its own does not produce psychoactive effects. It was also noted that approved prescription medicines have to meet quite stringent requirements regarding controls around dosage, concentration and stability among other testing criteria.  Currently, under section 29 of the Medicines Act 1981, there is an exemption for medical practitioners to prescribe unapproved medicines. Non-pharmaceutical forms do not need to meet the same requirements as approved prescription medicines.  MoH considers that CBD, even in the absence of THC, is a controlled drug under the isomer provisions of MoDA and it has administered the Medicines and Misuse of Drugs Acts in accordance with this view. If CBD is de-scheduled from MoDA to be a prescription medicine only, prescriptions will still be required to be in possession of CBD. There was a discussion around what the potential implications would be for de-scheduling CBD regarding over prescribing and abuse. Though CBD can be converted to THC, abuse and conversion of CBD to THC is considered unlikely as CBD based medicines would most likely cost much more than buying cannabis off the street as well as having to go through the process of gaining a prescription to access the CBD medicine. Currently, individuals can carry on their person up to a month’s supply of controlled drugs into NZ with appropriate overseas prescriptions and proof that it was lawfully supplied overseas for the purpose of treating a medical condition..  To address the issue around THC content in CBD medicines, it was suggested that a THC content threshold be set, similar to the allowable threshold of THC in hemp. It was discussed if the limit should be two percent, in line with Australia, or 0.35 percent in line with the threshold for THC in hemp.  The Committee queried whether there was enough evidence presented to make a recommendation for an allowable THC threshold in CBD preparations. They were particularly interested in the processes that led to the 0.35 percent threshold of THC allowed in hemp in NZ and the two percent threshold of other cannabinoids allowed in CBD medicines in Australia. The question was also raised of what the THC content of cannabis generally is.  **Outcome:** The Committee deferred the decision to the next meeting as more information is needed regarding the process that lead to the 0.35 percent of THC content threshold being allowed in hemp and the two percent threshold of other cannabinoids allowed in CBD medicines in Australia. Research around the effects of consumption of two percent of additional cannabinoids in a CBD product also needs to be looked at by the Secretariat and brought to the Committee.  **Action:** Secretariat to find out the process that lead to the 0.35 percent threshold of THC content allowed in hemp and report back to the Committee.  **Action:** Secretariat to find out what the process was for the TGA reaching the two percent threshold of other cannabinoids allowed in CBD medicines.  **Action:** Secretariat to find out more information around concentration levels of THC in the average cannabis that is circulating in the NZ market.  **Action:** Secretariat to find out more information regarding effects of consumption of products containing different concentrations of THC.  **Action:** Secretariat to add CBD to the next agenda.  [redacted] and [redacted] left the meeting at 12.04pm |
| 6 | **Alpha-PVP**  Alpha-PVP is currently classified as a Class C controlled drug under the analogue provision in MoDA. However, increased knowledge of its presence in NZ (since 2013) and its known effects of violent and psychotic behaviours as well as being implicated in a number of deaths both domestically and internationally, and other serious events indicate that it may be more appropriate for it to be controlled in a higher schedule under MoDA. Alpha-PVP has no known therapeutic value.  It would appear that alpha-PVP is possibly being used as an alternative for methamphetamine due to the prevalence of alpha-PVP use in the lower North Island whereas methamphetamine use is more prevalent in the upper North Island.  There was a discussion regarding the associated risks of harm for alpha-PVP being in line with methamphetamine, which is a Class A controlled drug. It was then queried why the classification options presented in the technical paper did not include the option to schedule alpha-PVP as a Class A controlled drug given the associated risks of harm being in line with methamphetamine. It was advised that the options for classifying alpha-PVP were based on a number of factors. Firstly, alpha-PVP is a synthetic cathinone and has functional similarities to pyrovalerone, which is scheduled as a Class B2 controlled drug. Secondly, to keep in line with its Schedule 2 status under the UN Convention on Psychotropic Substances. Lastly, almost all of the reported deaths involved poly-drug use, so it is difficult to pin point alpha-PVP as being a definitive factor. It was also noted that it is easier to schedule substances higher than to de-schedule or reschedule to a lower Class under MoDA.  **Outcome:** The Committee decided that the amount of deaths, violent and psychotic behaviours associated with the use of the drug as well as the potential for dependence was enough justification to put forward the recommendation to schedule alpha-PVP as a Class A controlled drug.  **Motion:** [redacted] moved that alpha-PVP be put forward for classification as a Class A controlled drug under MoDA to align it with methamphetamine due to its high risk of harm. Scheduling alpha-PVP as a Class A drug would also have a deterrent effect on substitution for Class B scheduled drugs such as MDMA and NBOMes. The motion was seconded by [redacted]. The Committee voted unanimously in favour.  **Action:** Secretariat to begin process to schedule alpha-PVP as a Class A controlled drug under MoDA. |
| 7 | **Break for lunch 12.30pm – 1pm** |
| 8 | **Hypophosphorous Acid and other Precursors**  At the previous meeting, the Committee considered a paper from NDIB that was produced in 2013 that looked at precursor chemicals, hypophosphorous acid in particular. Since the last meeting, NDIB have been asked to put together a paper that looks at a number of precursors to be considered together. Hypophosphorous acid, red phosphorous, phosphorous acid, iodine and hydriodic acid have been identified by ESR and Police as being primary industrial chemicals that are misused in the illicit manufacture of methamphetamine, however these products have a number of legitimate uses. There are still significant amounts of precursors being seen coming into the country, which indicates that methamphetamine is still being manufactured in NZ. The technical paper proposed that the named precursor chemicals be put forward for scheduling under the precursor provision in MoDA.  One of the concerns previously raised was the impact that scheduling the named chemicals would have on industry as there are multiple legitimate uses. NDIB have already been in contact with Responsible Care, who represents the majority of NZ’s major manufacturers and importers of hazardous substances. Responsible Care had consulted industry and were in support of the proposal to schedule the named precursors under MoDA. Police are still finding a significant number of these chemicals amongst organised crime. Scheduling the named precursors under MoDA would act as a deterrent to those supplying precursors for illicit purposes.  There was a discussion around whether there were already provisions under the Hazardous Substances and New Organisms Act 1996 (HSNO). However, it was noted that even if the named precursor substances were regulated under HSNO, it doesn’t have any regulations for importation monitoring; only labelling, storage and transport requirements.  It was also noted that there is already a provision under MoDA that covers possession of precursor substances and the supply, production or manufacture of precursors intended for illicit use. However knowledge of the illicit end use has to be proven (Section 12A and 12AB, MoDA). Scheduling the named substances under part 2 schedule 4 in MoDA would give Customs more search powers around import and export which may make some of the elements of an offence easier to prove (Section 36, MoDA). Scheduling the named precursors under MoDA do not appear to have any additional burdens to industry as there are no licensing requirements.  **Outcome:** The Committee agreed to put forward hypophosphorous acid, red phosphorous, phosphorous acid, iodine and hydriodic acid to be scheduled under part 2, schedule 4 under MoDA.  **Motion:** [redacted] proposed that hypophosphorous acid, red phosphorous, phosphorous acid, iodine and hydriodic acid be included as precursor chemicals under part 2 of Schedule 4 under MoDA on the basis that all five substances are used in the manufacture of methamphetamine in NZ as well as potentially being then on-sold internationally. The motion was seconded by [redacted]. The Committee were unanimously in favour.  **Action:** Secretariat to begin the process of scheduling hypophosphorous acid, red phosphorous, phosphorous acid, iodine and hydriodic acid chemicals under part 2 schedule 4 in MoDA. |
| 9 | **Methylone and Mephedrone**  Methylone and mephedrone are both synthetic cathinone’s that have psychoactive effects that are currently scheduled as Class C7 drugs under MoDA. It was noted that although there is less of a history of individual and community harm compared with alpha-PVP as well as not having a growing market in NZ, the risk of harm was substantial enough to be put forward for re-classification to align with a Class B classification. Both methylone and mephedrone fit with the principle of aligning their classification with already scheduled cathinone’s as Class B controlled drugs. It was noted that the difference between Class B1 and B2 is a dependence factor. Class B1 drugs have a higher risk of dependence than class B2 drugs.  **Outcome:** The Committee decided to put forward the recommendation to schedule both methylone and mephedrone as Class B2 controlled drugs under MoDA instead of Class B1 due to the low index of dependency.  **Motion:** [redacted] proposed that both Methylone and Mephedrone be put forward for scheduling as Class B2 controlled drugs under MoDA due to their high risk of harm and low index of dependency. This was seconded by [redacted]. All Committee members were unanimously in favour.  **Action:** Secretariat to begin the process to schedule both methylone and mephedrone as Class B2 controlled drugs under MoDA. |
| 10 | **Break for afternoon tea 2pm – 2.15pm** |
| 11 | **Submission process to the EACD**  In order to create more transparency between the Committee and the general public, the Secretariat had been working on a formalised process for providing submissions to the Committee. The Secretariat asked if the Committee would accept public submissions and what level of detail would be required of public submissions. It was recognised that public submissions would span a wide range of expertise and the contents of these submissions would vary from application to application. The Secretariat wants to set out a template that will be acceptable for the public. The proposed process would also involve a consultation period and would require that the agenda is made public in advance.  The risks around accepting public submissions was discussed. Based on feedback received, it appears that the public seem to have a misconception as to what the function/purpose of the EACD actually is. The Committee suggested that the Secretariat make a public statement to clarify what the purpose/function of the Committee actually is.  **Outcome:** The Committee were not in favour of public submissions due to potential privacy issues it would bring as well as the additional workload for the Secretariat, but acknowledged the fact that more transparency was needed for the public. The function and purpose of the Committee needs to be clarified to the public via a statement on the website. It was suggested that the papers, agenda and minutes be published on the website formatted in an appropriate way to increase transparency to the public.  **Action:** Secretariat prepare a statement from the Minister/Ministry of Health to add to the website clarifying the function and purpose of the Committee to the public and to set up a space for publishing the agenda and minutes. |
| 12 | **EACD Guidelines - update**  Under the National Drug Policy, one of the main actions for 2017/18 is for the Government to work more closely with the EACD to ensure that harm minimisation is a central feature of drug classification assessments. The Secretariat advised that the Ministry of Health have started a written plan/guidelines which will cover a clear definition of harm, classification advice and a work plan.  **Action:** Secretariat to send out EACD guidelines to Committee once it is closer to completion. |
| 13 | **Any other Business**  There was a brief discussion around the progress of the tramadol item. The Committee had previously agreed that warnings, better education and resources to prescribers to target inappropriate prescribing would be the most appropriate way to deal with abuse as opposed to scheduling tramadol under MoDA.  The Committee had previously agreed to continue to monitor abuse and inappropriate prescribing of tramadol and would look at potentially scheduling tramadol in 2017 pending further information.  It was also requested that the reported data also include how many individuals are going to different doctors and pharmacies to access tramadol and how many people are being prescribed more than the maximum dose.  **Action:** Secretariat to look at how many individuals are getting prescriptions for tramadol from multiple doctors and pharmacies as well as the number of individuals being prescribed more than the maximum doses to include in the annual reporting. |
| 14 | **Future meetings**  The next meeting will be held tentatively in early October. Exact date TBC pending confirmation of the dates for the Ministry of Health building move. |

The meeting closed at 3.10pm

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| **Item** | **Action** | **Who** | **Completed** |
| 1 | Liaise with IACD Secretariat regarding lines of communication with respect to what emerging substances for EACD to consider. | Secretariat |  |
| 2 | Speak to some General Practitioners that have expertise in addiction and work closely with Police with regard to finding someone to replace [redacted] as the community medicine representative on the Committee. | [redacted] |  |
| 3 | Speak to The Royal New Zealand College of General Practitioners and Pharmacology and Therapeutics Advisory Committee (PTAC) for recommendations to replace [redacted] as the community medicine representative on the Committee. | Secretariat |  |
| 4 | Find out the process that led to the 0.35 percent threshold of THC content allowed in hemp and report back to the committee. | Secretariat |  |
| 5 | Find out what the process was for the TGA reaching the two percent threshold of other cannabinoids allowed in CBD medicines. | Secretariat |  |
| 6 | Find out more information around the average levels of THC in cannabis that is circulating in the NZ market. | Secretariat |  |
| 7 | Find out more information regarding effects of consumption of products containing different concentrations of THC. | Secretariat |  |
| 8 | Add CBD to the next meeting agenda | Secretariat |  |
| 9 | Begin process to schedule alpha-PVP as a Class A controlled drug under MoDA. | Secretariat |  |
| 10 | Begin the process of scheduling hypophosphorous acid, red phosphorous, phosphorous acid, iodine and hydriodic acid chemicals under part 2 schedule 4 in MoDA. | Secretariat |  |
| 11 | Begin the process to schedule both methylone and mephedrone as Class B2 controlled drugs under MoDA. | Secretariat |  |
| 12 | Prepare a statement from the Minister/Ministry of Health to add to the website clarifying the function and purpose of the Committee to the public and to set up a space for publishing the agenda and minutes. | Secretariat |  |
| 13 | Look at how many individuals are getting prescriptions for tramadol from multiple Doctors and pharmacies as well as the number of individuals being prescribed more than the maximum dose to include in the annual reporting for tramadol. | Secretariat |  |