**Minutes** 

**Expert Advisory Committee on Drugs meeting**

|  |  |
| --- | --- |
| **Date:** | Thursday 16 April 2015 |
| **Time:** | 10am - 3pm |
| **Location:** | Eagle Room, Miramar Links, 1 Stewart Duff Drive, Miramar |
| **Acting Chair:** | Dr Helen Moriarty |
| **Attendees:** | Committee – Dr Helen Moriarty, Detective Superintendent Gregory Williams, Dr Vicki Macfarlane, Dr Keith Bedford, Mr Christopher Howley, Ms Lynette Knox, Dr Jaki Horn, Mr Richard Schmidt (on behalf of Malcolm Luey)  Technical Advisor – Dr Dennis Page (Medsafe)  Secretariat – Alison Cossar, Haley Ataera, Sarah Condon, Cherish Low (minutes)  Observer – Fraser Colson (Office of the Psychoactive Substances Regulatory Authority) |
| **Apologies:** | Associate Professor Cynthia Darlington, Dr Stewart Jessamine, Mr Malcolm Luey, Dr Darren Hunt |

|  |  |
| --- | --- |
| **Item** | **Notes** |
| 1 | **Welcome, Introductions and apologies**  The Secretariat advised that the Chair (Associate Professor Cynthia Darlington) was unable to attend the meeting due to the cancellation of her flight. In accordance with the Committee handbook, Dr Helen Moriarty was nominated by the Chair to chair the meeting which was accepted by the rest of the Committee.  The Committee and Secretariat introduced themselves and their areas of expertise.  The Secretariat nominated [redacted] from Medsafe to attend the meeting as a technical advisor for the discussion on analogue and precursor provisions.  Apologies were received from Dr Stewart Jessamine, Associate Professor Cynthia Darlington, Dr Darren Hunt and Malcolm Luey who is currently on secondment. [redacted] from the Ministry of Justice attended on behalf of Malcolm Luey. |
| 2 | **Conflicts of interest**  A conflict of interest declaration was submitted by [redacted].  Conflicts of interests only apply to Committee members but his conflict was duly noted. As a non-committee member, the impact of [redacted]conflict is likely to be minimal because he has no voting rights. |
| 3 | **Confirmation of previous minutes**  It was noted that the Secretariat had added an amendment to the previous minutes clarifying the process for categorising DMAA as a medicine.  **Outcome**: It was moved by [redacted] that the minutes of the previous meeting be accepted which was seconded by [redacted]. |
| 4 | **Terms of reference**  There were no comments made in regard to the Secretariat’s amendments to the Terms of Reference.  **Outcome:** The document will be finalised out of session once the Committee agrees on the process for receiving submissions for classification, public consultation and consideration of submissions (see agenda item 5). |
| 5 | **Two stage assessment process**  A two stage process for drug assessment was discussed at the previous meeting. The Secretariat provided a more detailed description of the process, as well as an alternative process that would be more streamlined. Due to the change in Secretariat from the last meeting, the Secretariat proposed that the Committee hold two meetings a year instead of three to four and adopt a one stage assessment to align with this.  The Committee discussed the merits around the two options. The assessment process that is adopted will be dependent on what information is available for the specific drug that is being assessed.  **Outcome:** The process for drug assessment will be finalised out of session once the Secretariat has provided a more detailed description for comment.  **Action:** Secretariat to provide a more detailed description of the one stage process to forward to the Committee out of session.  *Update on consultation*  [redacted]    The Committee discussed the importance of transparency and public input but acknowledged the potential issues that could arise with public consultations. Options discussed for the opportunity for the public to participate included:   * being able to submit items for inclusion on the agenda, subject to approval of the item by the Chair * and/or being asked for submissions on pre-set agenda items.   The Secretariat also briefly discussed different options that would ensure that public submissions would meet criteria for quality and relevance.  **Outcome:** The Committee were all in favour of public submissions. The process for consultation would be finalised out of session pending a guidance document provided by the Secretariat.  **Action:** Secretariat to provide a guidance document for the public consultation process for the Committee to consider out of session. |
| 6 | **Handbook**  It was clarified that the Committee Handbook is an internal document for members only and will not be for public distribution.  **Action:** Secretariat to amend the error in section 3.0 under General expectations.  The issue of availability of committee members for meetings was discussed, and whether or not it would be appropriate for committee members to nominate a stand in in their absence. It was also discussed whether or not attendees that were standing in for appointed members would have voting rights, and if they would be able to form part of the quorum.  **Outcome:** It was moved by [redacted] that when a committee member from a statutory body is unavailable to attend a meeting for a legitimate reason, they are able to nominate an appropriate person with the approval of the Chair to attend on their behalf prior to the next meeting This was seconded by [redacted].  **Action:** Secretariat to get advice from Health Legal whether or not a stand in committee member can cast a vote and if they are able to form part of the quorum. |
| 7 | **Website**  *7.1 Update to current website*  The Secretariat gave a brief overview of the proposed changes to the web page. The issue around confidentiality of member contact details was raised. The Secretariat clarified that the committee member contact details would not be published on the website or be available to the public.  The “Public input to the drug classification process” section on the web page needs to be updated to reflect the decided process for public consultations discussed in agenda item 5.  The format, timing of release and confirmation process of the technical papers and minutes that will be made available on the website was also discussed.  **Outcome:** Papers published on the website, including technical papers, agendas and minutes, would need to be written appropriately for external release. The Secretariat would need to consult with Health Legal. It was suggested by the Secretariat that the minutes be confirmed out of session. Minutes will be circulated to the Committee for comment and would be confirmed electronically.  **Action:** Secretariat to update [redacted] title to reflect his current position and add areas of expertise to the list of members on the website.  *7.2 Shared workspace*  The idea behind the shared workspace initiative is to allow easier information sharing between different organisations. This space is hosted by the Department of Internal Affairs. A Realme login is required. Agendas, minutes and technical papers will be posted in the work space which will be able to be edited.  **Outcome:** The Committee requested that instead of hardcopy hand outs of meeting papers, a data projector be set up to display the meeting papers from the shared workspace for future meetings. The Secretariat will look into this for the next meeting. Nominated persons that will be standing in for committee members who are unable to attend meetings will also be given access after approval from the Chair.  **Action**: Secretariat to send out invites for shared workspace. |
| 8 | **Working schedule of substances**  At the previous meeting, it was proposed that the Committee systematically go through substances in the schedule. The Office of the Psychoactive Substances Regulatory Authority (OPSRA) has only recently been appointed as the Secretariat to the EACD. The Secretariat advised that due to other work priorities as well as providing technical papers for meetings, they would be unable to commit to the amount of work required to systematically work through the schedule of substances. The Secretariat suggested that the Committee focus on scheduling new drugs, which will likely be psychoactive substances, and if already scheduled drugs require review, they be approached on a case by case basis. The Committee agreed. |
| 9 | **Break for morning tea** |
| 10 | **Update on DMAA**  At the previous meeting, the Committee agreed that DMAA should be referred to the Medicines Classification Committee for consideration as a medicine as DMAA does not meet enough of the criteria or reach the appropriate harm threshold required to be classified under MoDA. The Secretariat has since clarified that DMAA needed to be referred to the Medicines Categorisation Committee first to decide if DMAA should be categorised as a medicine. The Secretariat advised that the Medicines Categorisation Committee met and decided that products containing DMAA are medicines due to its decongestant properties. The Medicines Categorisation Committee has referred DMAA to the Medicines Classification Committee who will then determine what type of medicine it will be classified as. DMAA has been added to the agenda for the Medicines Classification Committee meeting that is likely to be held in October or November 2015.  **Action:** The Secretariat will inform the EACD of the Medicines Classification Committee decision on DMAA. |
| 11 | **Analogue and precursor provisions**  [redacted] presented some notes on understanding aspects of the MoDA with particular regard to analogue provisions. [redacted] was nominated by the Secretariat to provide technical input for this discussion. See “Notes on Understanding Aspects of the Misuse of Drugs Act paper”.  [redacted] will forward these notes to the Secretariat for dissemination to the Committee.  In brief, the MoDA makes reference to isomers, esters, ethers and salts of any substance listed in schedule 1, clause 1; in parts 1, 2 and 3 of schedule 2; in clause 2 of part 1 of schedule 3 and in clause 1 of parts 3, 4 and 5 of schedule 3 of MoDA. [redacted] explained the application of these inclusions. This is because these forms or derivatives are easily converted to the parent substance.  The analogue provisions of MoDA apply to structures that are substantially similar to that of any controlled drug. This provision is much less clearly defined than the provisions described above, but the important point to note is that this provision is based on structural similarity alone. If a substance is deemed to be of sufficient structural similarity to a controlled drug, it is subject to regulation under MoDA as a Class C controlled drug, irrespective of whether there is evidence of harm and irrespective of the classification of the listed controlled drug. This constitutes a ‘safety net’ provision and was introduced as a means to counter the trend for the appearance of variants of known sought-after drugs. This was prior to the introduction of the Psychoactive Substances regime.  *11.1 Phenethylamine*  The Secretariat gave a brief overview providing preliminary information in consideration of scheduling phenethylamine or the substituted phenethylamines as precursor substances under MoDA. Phenethylamine, though very structurally similar to a number of analogues, is hard to convert and is, therefore, not of concern from a regulatory perspective.  **Outcome:** [redacted] advised that the vast majority of substituted phenethylamines would already fall under Class C of MoDA as amphetamine analogues, so do not require scheduling. The Committee agreed.  **Action:** The Secretariat will monitor the substituted phenethylamines that are brought to their attention (via Customs and Police for example) to see which ones aren’t captured by the Psychoactive Substances Act or the Class C amphetamine analogues under MoDA. The Committee may choose to consider any substituted phenethylamines that are not captured under the Psychoactive Substances Act or MoDA for scheduling under MoDA at a later date. |
| 12 | **NBOMe**  *12.1 Update paper*  The Committee agreed at the previous meeting to a provisional recommendation that 25B-NBOMe, 25C-NBOMe and 25I-NBOMe be classified as Schedule 2, Part 1 (Class B1) under MoDA subject to consideration of any further information available on teratogenicity, international controls around NBOMes and the prevalence of NBOMe use in New Zealand before making a final classification decision. The update paper included additional information on teratogenicity and international classification and experience in other jurisdictions. No further information on the prevalence of use in New Zealand was available.  *12.2 Group classification and presumption for supply*  [redacted] spoke to the “Proposed Classification of NBOMe series substances under the NZ Misuse of Drugs Act” paper which provided two options around the scheduling of the NBOMe drug family.  Option one:  **NBOMe series substances**: Any substance, not otherwise listed, which contains a phenyl ring-substituted dimethoxyphenethylamine nucleus that is also substituted at the nitrogen atom of the amino group with a benzyl substituent. Either or both benzene rings may also carry one or more of the following radicals:  alkyl (containing up to six carbon atoms), or alkoxy (containing up to six carbon atoms), or alkylamino (containing up to 6 carbon atoms), or alkylthio (containing up to 6 carbon atoms), or halogen, or nitro.  This proposed listing would cover a very broad range of NBOMe and closely-related substances but not all of those listed in the 23 October 2014 EACD paper (e.g. 2CBFly-NBOMe, 2CBCB-NBOMe, 25G-NBOMe would not be included). However, these and other similar substances would still be included in the Controlled Drug Analogue “safety net” and would be Class C Controlled Drugs as having “…a structure substantially similar to that of any controlled drug”.  Option two:  **NBOMe series substances**: Any substance, not otherwise listed, which contains a 2,5-dimethoxyphenethylamine nucleus carrying any one of the following radicals, in the 4-position on the benzene ring:  hydrogen, or alkyl (containing up to six carbon atoms), or alkoxy (containing up to six carbon atoms), or alkylamino (containing up to 6 carbon atoms), or alkylthio (containing up to 6 carbon atoms), or halogen, or nitro;  and in addition,  is substituted at the nitrogen atom of the amino group with a benzyl substituent, in which the phenyl ring carries hydrogen or one methoxy- radical in the 2,3 or 4- positions.  This proposed listing is significantly ‘narrower’ in scope compared to Option one. A number of substances listed in the 23 October 2014 EACD paper would not be included, but this version still covers many substances, such as the 30+ listed in the Casale and Hays *Microgram Journal* paper.  There was a discussion amongst the Committee around the appropriateness of the two options.  [redacted] also gave a third option that would schedule the three most commonly seen NBOMes (25B-NBOMe, 25C-NBOMe, 25I-NBOMe) as class B1. Subsequently, most other known NBOMes would automatically be captured as Class C under the controlled drug analogue provisions of MoDA.  The Secretariat also advised that if there are any other current or future NBOMes that fall outside the scope of what was decided at this meeting, by default, they will be captured under the Psychoactive Substances Act if they have psychoactive effects. Any NBOMe that is not captured under the proposed MoDA scheduling and that is **not** psychoactive is unlikely to be abused and would likely not require regulation.  **Outcome:** Under the recommendation made by [redacted], the Committee agreed that option three was the most appropriate option to schedule the named NBOMes.It was moved by [redacted] that 25B-NBOMe, 25C-NBOMe and 25I-NBOMe be scheduled as Class B1. This was seconded by [redacted]. All were in favour.  **Note:** [redacted] refrained from voting for any motions put forward to prevent invalidating any decisions made on the grounds that he was not an appointed member.  [redacted] made the following recommendation on the presumption for supply:  NBOMe series substances, 25 milligrams or 25 flakes, tablets, capsules or other drug forms, each containing some quantity of the drug.  This proposed presumption for supply implies an average dosage unit amount of 1000 micrograms or 1 milligram.  The Committee agreed with [redacted] recommendation. |
| 13 | **Break for lunch** |
| 14 | **Tramadol**  At the previous meeting the Secretariat presented an update paper on tramadol. Tramadol was previously considered by the EACD but a decision to classify it as a controlled drug was subject to further information. The Secretariat provided a revised assessment which includes information on its international abuse profile and likelihood or evidence of abuse in New Zealand. Three classification options were proposed:  Option one: No change – tramadol would continue to be regulated as a prescription medicine under the Medicines Act in an approach similar to that adopted by Australia, Canada and Germany.  Option two: Schedule tramadol as a Class C controlled drug under MoDA. This approach is similar to that adopted by the UK and the US.  Option three: Adopt any combination of the following options.   * Request PHARMAC to cease funding tramadol. * Request PHARMAC to preferentially fund formulations that are considered to be harder to abuse. * Request that Medsafe and PHARMAC undertake education campaigns for prescribers to raise awareness of the safety profile of tramadol.   The Committee discussed the evidence of abuse and addiction in New Zealand, particularly since it became funded by PHARMAC in 2010. The committee also discussed the potential issues with the prescribing process and misconceptions around the safety of tramadol amongst doctors.  **Outcome:** The Committee agreed thatmore information on the evidence of harm in New Zealand is needed before any concrete decisions can be made whether or not to schedule tramadol as a controlled drug.  **Action:** [redacted] to liaise with NDIB regarding a review of the paper on tramadol which will inform a later discussion for the EACD.  **Action:** The Secretariat to liaise with the Ministry of Health to arrange consultation with industry and PHARMAC on the potential for scheduling tramadol as a Class C controlled drug under MoDA. |
| 15 | **Future meetings (dates and frequency)**  The Secretariat previously proposed that the Committee hold three to four meetings a year. However, due to the increased work load for the Secretariat, this proposal was revised to suggest two meetings a year. The Committee agreed.  It was suggested that meetings be held early April and early September. The Committee agreed on these tentative dates.  **Action:** Secretariat to confirm the exact date of the next meeting.  *Agenda items for next meeting*  Hypophosphorus acid as a precursor  Zopiclone  Zolpidem |

The meeting closed at 2:19pm

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | **Action** | **Who** | **Completed** |
| 1 | Provide a more detailed description of the one stage process to forward to the Committee out of session. | Secretariat |  |
| 2 | Provide the Committee with a guidance document for the public consultation process. | Secretariat |  |
| 3 | Amend error in handbook under section 3.0 General expectations. | Secretariat |  |
| 4 | Get advice from Health Legal on whether or not a seconded committee member can vote and if they are able to form part of a quorum. | Secretariat |  |
| 5 | Update [redacted] title to reflect his current position and add areas of expertise to the list of members on the website. | Secretariat |  |
| 6 | Send out invites to the Committee for the shared workspace. | Secretariat |  |
| 7 | Inform the EACD of the Medicines Classification Committee decision on DMAA. | Secretariat |  |
| 8 | Liaise with NDIB regarding a review of the paper on tramadol. | [redacted] |  |
| 9 | Liaise with Medsafe regarding consultation process for the scheduling of tramadol. | Secretariat |  |
| 10 | Confirm date for next meeting. | Secretariat |  |