

EXPERT ADVISORY COMMITTEE ON DRUGS

Thursday 13 November 2008, 9.00 am– 2.00 pm
Medsafe, 10 Brandon Street, Deloitte House, Level 6, Wellington

EACD MEMBERS PRESENT

Dr Ashley Bloomfield (Chair)	Dr Stewart Jessamine (via teleconference for Item 4)
Dr Keith Bedford	Dr Tim Maling
Paul Campbell	Alison Stephens (for Rajesh Chhana)
Adrienne Fruean	Detective Superintendent Win van der Velde

EACD SECRETARIAT PRESENT

Bronwen Hicks	Mark Heffernan
Chris Laurenson	Bruce Atmore

GUESTS PRESENT

Detective Senior Sergeant Stuart Mills (National Drug Intelligence Bureau)	
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1 WELCOME AND APOLOGIES

Apologies were received from Dr Geoffrey Robinson, Professor Doug Sellman, and Dr Helen Moriarty.

The Chair welcomed Bronwen Hicks, a new member of the Secretariat to the meeting.

2 CONFIRMATION OF 12 JUNE 2008 MINUTES

The minutes from the 12 June 2008 meeting were confirmed and authorised to be made publicly available on the National Drug Policy website.

3 MATTERS ARISING FROM 12 JUNE 2008 MEETING

3.1 Tramadol Item 2.2

Tramadol is to be discussed under agenda item 4

3.2 BZP-Free ‘Party Pills’ Item 6

Issue: The Secretariat had been requested to facilitate a discussion with the ‘party pill’ industry to assist in providing ESR with a reference standard to confirm the testing of BZP-free party pills. The Secretariat was to prepare a response to a letter from the Executive Director of the New Zealand Drug Foundation to inform the Foundation of the Committee’s consideration of BZP-free ‘party pills’.

Outcome: The Secretariat has been in ongoing contact with ESR and New Zealand Customs to identify a trusted international supplier of a reference standard for this substance. It is understood that ESR is awaiting delivery of this reference standard. The Committee noted that there is variation in the chemical make up of substance purported to be included in BZP-free ‘party pills’.

The Chair has sent a letter to the Executive Director of the New Zealand Drug Foundation informing him of the Committee’s view that there is not sufficient evidence available to make any recommendations at this time but will keep a watching brief on any developments.

3.3 Clarification of EACD Advice on Salvia Divinorum Item 7

Issue: The Chair was to obtain out of session confirmation from members not present at the meeting that processed extracts of salvia divinorum only should be scheduled, and not the raw salvia divinorum plant and then write to the Minister with the Committee’s revised advice.

Outcome: The updated advice of the Committee has been accepted by the Minister. The scheduling of preparations of salvia divinorum as restricted substances is currently being progressed.

3.4 Date of Next Meeting Item 9

Issue: The Secretariat was to update the EACD’s working schedule of substances to include most recent reviews/recommendations, and incorporating it into a discussion paper for the EACD to review and develop its strategic plan.

Outcome: The Secretariat has updated the working schedule of substances and a suggestion was made to move from a reactive to a proactive approach when assessing the controlled drug schedules and to link in with the Law Commission led review of the Misuse of Drugs Act 1975.

4 TRAMADOL

Dr Stewart Jessamine joined the discussion via teleconference.

Reference: paper provided by the Secretariat.

Issue: The Secretariat updated the EACD on progress with the classification of tramadol as a Class C2 controlled drug under the Misuse of Drugs Act 1975 (MoDA). The Committee also discussed some concerns which have been raised by industry and health agencies about the classification.

Discussion:

The Committee discussed the use of tramadol internationally and a member raised concerns about the proposed classification of tramadol from a regulatory point of view. It was noted that evaluations from the World Health Organization, United States of America, Europe and Canada showed while abuse can and does occur, it is at a very low rate and significantly less than that seen for other related analgesics.

The Committee discussed the uptake of tramadol in New Zealand and noted that it is not used to the same extent as codeine and paracetamol and that there is no evidence that tramadol is being diverted or abused to the same extent as other step two analgesics such as codeine and dihydrocodeine. Tramadol was not being widely prescribed, was not identified in toxicology reports and was not being illegally imported in significant quantities. The Committee noted that should PHARMAC decide to subsidise Tramadol, its use would inevitably increase and the potential for diversion could increase.

One member suggested that the impact of classification of tramadol on pharmaceutical companies should be considered separately.

The Committee noted that there is a large usage of this drug in hospitals and nausea is noted as a very common side effect.

The Committee noted that tramadol is not as effective if injected, and for it to be effective it is necessary to consume comparatively large quantities orally when compared to step two analgesics.

The Committee discussed the proposed options concluded that there was insufficient evidence on the potential harms from tramadol justify a classification at this time. The Committee agreed to recommend that the classification process be put on hold for a two year period to allow further evidence to be gathered of any increase in misuse related to a PHARMAC decision to subsidise tramadol in the outpatient setting and whether it was posing a significant problem in New Zealand.

Outcome: The Committee discussed the proposed options and noted the results of the targeted consultation with New Zealand distributors of tramadol regarding the proposed classification. The Committee also noted that concerns have been raised by PHARMAC and one Committee member, in addition to the pharmaceutical companies consulted, regarding the classification of tramadol.

Actions:

The EACD to recommend to the Minister that the classification process be put on hold for a two year period to allow further evidence to be gathered on any misuse associated with tramadol.

The Chair to write to PHARMAC regarding the EACD's concerns about increased diversion and non therapeutic use of tramadol should it be subsidised. The Chair to include advice to PHARMAC that the EACD will gather data in order to reassess the classification issue in two years.

The Secretariat to obtain PHARMAC data as part of the collation process for evidence.

The Secretariat to write to the Medicines Adverse Reactions Committee regarding concerns about the side effect profile.

5 Further consideration on 1,3 dimethylamylamine (DMAA)

Reference: paper provided by the Secretariat.

Issue: The Secretariat updated the Committee with additional information relating to the availability and potential harms of 1,3 dimethylamylamine (DMAA) in New Zealand.

Discussion: The Secretariat advised the Committee that DMAA came to the Ministry of Health's attention by its indicative presence in some BZP-free 'party pills' following the reclassification of BZP in April. The Secretariat advised that as there is no international peer reviewed research available on this substance, it is possible to provide only an overview of the market for DMAA in New Zealand and a speculation of the pharmacodynamics of DMAA for the Committee's information.

Recently four individuals in the Waikato region, after consuming this substance, were admitted to hospital. Following this the Ministry of Health requested a voluntary suspension of the sale of DMAA when sold in powder form. Initial indicators were that the majority of retailers have complied with this request. However DMAA-containing 'party pills' are still widely available. It is also considered unlikely that retailers will voluntarily suspend sales indefinitely.

There was discussion around the possibility of DMAA triggering the threshold of a hazardous substance under the Hazardous Substances and New Organisms Act 1996 (HSNO). The Secretariat advised that the Ministry of Health has met with the ERMENZ concerning DMAA. ERMENZ advised that DMAA may possibly trigger the provisions of the HSNO Act but a formal assessment would need to be undertaken. Such an assessment could not be resourced by ERMENZ. The Committee agreed that the HSNO framework would be an effective tool to risk management of foreign substances entering the country.

The Chair commented that it is promising to know that regulatory processes other than the MoDA can be further explored.

The Secretariat advised the Committee that DMAA could be recommended as a restricted substance if it met the criteria. Regulations could be made to prohibit the availability of the substance in powder form.

The Committee agreed that no further action was to be taken under the Misuse of Drugs Act 1975 and that the Secretariat would continue to monitor the harms from DMAA in New Zealand and liaise with EMANZ for action under the HSNO Act should the need arise.

Outcome: The Committee agreed that no further action was currently required under the Misuse of Drugs Act 1975 but that the Secretariat should continue to monitor the harms from DMAA in New Zealand and liaise with the Environmental Risk Management Authority of New Zealand (ERMANZ) for action under the Hazardous Substances and New Organisms Act should the need arise.

Action:

The Secretariat to continue to monitor the harms from DMAA in New Zealand and to liaise with ERMANZ for action under the HSNO should it be warranted.

6 Norephedrine

Reference: paper provided by the Secretariat and a letter from the National Drug Intelligence Bureau (NDIB).

Issue: The Secretariat provided an update on norephedrine following a letter from the NDIB that norephedrine is listed in a schedule to a United Nations drug convention and therefore should be appropriately classified in New Zealand.

At the 28 June 2007 meeting it was agreed that there was insufficient evidence to recommend a classification and that Police would monitor clandestine seizures for a 12 month period and report back to the Committee as to whether norephedrine was being used as a precursor substance in the manufacture of amphetamine.

Discussion: The Chair commented that a formal assessment on norephedrine was undertaken when the Committee last considered this substance.

The Committee was informed of an instance of a criminal group attempting to obtain a quantity of norephedrine from unidentified premises, which suggested that there is knowledge of norephedrine's potential to be used as a precursor.

Norephedrine has been listed in a schedule to the United Nations drug conventions and the Committee noted that New Zealand may be in breach of this convention by not placing controls around this substance. One member advised that no importers are bringing this substance in for use as a decongestant and queried the Committee on evidence of it being used domestically as a precursor. The Committee noted that norephedrine is no longer widely used in pharmaceutical preparations and that there would be only a limited effect on industry should this substance be classified.

The Committee noted that there is little difference between pseudoephedrine, ephedrine and norephedrine; however it is the availability of both pseudoephedrine and ephedrine which allow these two drugs to be more commonly diverted into the manufacture of controlled drugs in New Zealand.

The Chair noted that precursor substances are listed in the specific schedule 4. There was debate over whether norephedrine should be classified in Schedule 2 (Class B) or Schedule 3 (Class C) or 4 (Precursor Substances). The Committee also noted that, as norephedrine can be used to synthesise a Class B drug, it could be argued that its scheduling should be proportionate to that of precursors used to synthesise Class A drugs, such as methamphetamine. It was also noted that norpseudoephedrine is classified as a Class B2 controlled drug and norephedrine has a similar relationship to norpseudoephedrine as ephedrine has to pseudoephedrine.

Members discussed offences and penalties, and the lack of knowledge on this particular substance. One member commented that norephedrine is relatively unknown and classification may draw attention to this substance and increase the possibility of flow-on effects.

Members also discussed the effect that a classification could have in deterring would be users of norephedrine.

The Chair advised that the EACD had considered, at its last meeting, a secretariat paper summarising the available evidence on norephedrine and that, in his view, the Committee had addressed to the extent possible the matters outlined in section 4B(2) of the Misuse of Drugs Act 1975. A member raised the importance of examining whether the use of the substance has the potential to cause death. The Committee also considered the possibility of psychological and physical dependence.

The Committee discussed the presumption for supply and whether there is sufficient evidence available to recommend a limit at and over which norephedrine could be deemed to be possessed with intent to supply. The Committee agreed that while presumption for supply is a factor worth considering, it should not prevent a classification decision being reached at this stage.

The Committee discussed proposed classifications and noted that it is easier to raise a classification than lower it from one schedule to another. The Committee agreed to recommend to the Minister that norephedrine be scheduled as a Class B2 controlled drug. The Committee's recommendation was based, *inter alia*, on it having no therapeutic value and that its sole conceivable use in New Zealand would be for manufacture into amphetamine. The Committee further agreed that norephedrine should also be placed in Schedule 4 under the Act as it is also a precursor substance.

In addition, it would be necessary for the Committee to begin focusing on a presumption for supply level and to inform veterinarians, who may be affected by this decision. It was also noted that it will be necessary to consider storage matters.

Outcome: The Committee agreed to recommend to the Minister that norephedrine be classified in the second Part of the Second Schedule of the MoDA (Class B2) and Schedule 4 (Precursor Substances). It would also be necessary for the Committee to

then recommend a level at which norephedrine can be presumed to be possessed with intent to supply.

Action

The EACD to recommend to the Minister that norephedrine be classified in Part 2 of Schedule 2 (Class B2) and also Schedule 4 (Precursor Substances) of the Misuse of Drugs Act 1975.

The Secretariat on receipt of the Minister's acceptance of the recommendation to inform veterinarians of the Minister's decision to classify norephedrine.

The EACD to investigate a presumption for supply level for norephedrine for its next meeting.

7. Ministry of Health Update

Ketamine

The Secretariat updated the Committee on the progress of classifying ketamine. It was noted that a notice of motion is now required to be made in order for the Order in Council to be progressed in Parliament. The Secretariat advised that this classification will now need to be endorsed by the new Minister.

Implementation of Restricted Substances Regulations

The Committee noted that the Misuse of Drugs (Restricted Substances) Regulations 2008 have now come into effect providing for further controls around the marketing and availability of restricted substances.

The Secretariat also updated the Committee on the scheduling of salvia divinorum preparations as restricted substances, which are expected to be progressed when Parliament resumes.

Law Commission Review of Misuse of Drugs Act (MoDA)

The Secretariat updated the Committee on the Law Commission led review. The Committee noted that the report back to cabinet which has been scheduled for December 2008, had now been changed to March 2009.

8. Update on working schedule of substances/drugs needing to be classified

The Committee discussed the ways to proceed with working through the schedule of substances reclassification of drugs. The Committee noted that much of the work programme is emerging and it will be necessary to liaise with the incoming government.

The Secretariat advised that because drugs classified prior to 2000 were not systematically assessed according to the criteria for harm now registered, it was

necessary for the EACD to assess these substances to satisfy itself that they were appropriately classified.

The Chair requested member's views on suggested ways to proceed with the working schedule. It was suggested to target a number of substances per Committee meeting which may be considered to be out of place or have been brought to the Committee's attention. The reclassification of thalidomide has been recommended, and the classification of LSD has been raised as questionable. One member advised that if LSD was to be examined, hallucinogens needed to be looked at as a broader group. Another member advised that some hallucinogens could have a higher risk than some of the other Class A drugs. The Committee discussed whether it was relevant for some drugs to still exist in the controlled drug schedules, for example whether barbituates were still being manufactured and whether there was still evidence of trafficking. The Committee also noted that MDMA/ecstasy was recently listed near the bottom of a list of harmful drugs below cannabis and alcohol in one scientific report from the UK published in *The Lancet*.

Members agreed that they are confident about the classification of newer substances in the schedules, it is the classification of substances classified prior to the establishment of the EACD that may require examination. The importance of New Zealand keeping up with international developments was reinforced. It was also noted that the class system of A, B and C will be examined as part of the Law Commission review.

The Committee agreed to address the working schedule of substances. The Committee would begin by assessing a group of hallucinogens. One member advised that there is some intelligence held that can be reported on.

Action:

The EACD will consider hallucinogens at its next EACD meeting.

9. Discussion on EACD process for considering new substances

The Committee discussed the current EACD processes for consideration when examining drugs. It was noted 'chat rooms' would allow for people who hold views but may be hesitant to present that view in a formal setting. Engaging in consultation with the public should be part of policy development. It was noted, however, that this method could be very difficult to manage in terms of large amounts of incoming emails, unless it was moderated, and was probably beyond the EACD mandate.

There was discussion around the order in which the Minister should be approached with regard to recommendations. The Committee clarified that it is the Secretariat's responsibility to undertake consultation. A member commented that if information on items of EACD meetings was made obvious on the National Drug Policy website, industry and other stakeholders will have the opportunity to provide relevant information ahead of the Committee's consideration of substances. This would allow the Committee to receive submissions in a timely manner, and thus be able to advise the Minister on the impact of any recommendations regarding classification.

The Committee agreed that the following amendments to the process for examining drugs include:

1. Notification of the dates of upcoming EACD meetings, drugs to be discussed and the confirmed agenda are to be placed on the website
2. Notifying 'interested parties' if the EACD is performing full assessments; interested parties include: manufacturers, PHARMAC, professional groups and non-government organisations, e.g. the Drug Foundation. This leads to an opportunity to provide information to help inform the discussion against the EACD criteria set out in the MoDA
3. Ensuring recommendations to the Minister include advice on the impact on industry and other affected parties.

The Chair reminded the Committee of its obligation to publicise the Committee's business. For example the Committee could inform relevant Non Government Organisations that it is looking into particular substances, which in turn can liaise with their networks.

10. General Business

A member raised some information on recent drug trends in New Zealand. The Committee noted that some unusual substances have cropped up recently, for example Iodo-DMA (DOI), this is the Iodo-analogue of Br-DMA (DOB) which was a common hallucinogenic drug in New Zealand in the 1980s; and Bromo-LSD. According to the internet, DOI has an unusually slow onset of reactions and there is a risk that users might take additional doses because they experience little initial effect. The Committee noted that the EACD currently has no information on Bromo-LSD. Customs has made a number of submissions recently, however there is no analytical or toxicity data on this. The Committee noted that there is another drugs trend report due soon.

11. Proposed dates for 2009 meetings

The 2009 EACD meetings are scheduled for:

- Thursday 7 May
- Thursday 6 August
- Thursday 5 November

Action:

The Secretariat to send a reminder to the Committee on the proposed dates for 2009.

The meeting closed at 2.00pm.