EXPERT ADVISORY COMMITTEE ON DRUGS
Thursday 3 May 2007, 9.30am – 2.30pm
Terrace Room 3, Terrace Conference Centre, Level 2, St John House,
114 The Terrace, Wellington

EACD MEMBERS PRESENT

Dr Ashley Bloomfield (Chair)	Dr Geoffrey Robinson
Dr Helen Moriarty	Professor Doug Sellman
Dr Keith Bedford	Adrienne Fruean
Paul Campbell	Rajesh Chhana

EACD SECRETARIAT PRESENT

Olivia Tuatoko	Martin Woodbridge
Bruce Atmore	Mark Heffernan

INVITED GUESTS/EXPERTS

Win van der Velde	Dave Potaka
Una Jagose	

1 & 2 WELCOME AND APPOLOGIES

Apologies were received from Clinical Associate Professor Tim Maling and Gavin Jones. Rajesh Chhana gave apologies for lateness.

Acting Assistant Commissioner Gavin Jones has been appointed as the New Zealand Police representative on the EACD. Detective Superintendent Win van der Velde attended the meeting on behalf of Commissioner Jones.

Dave Potaka, Detective Senior Sergeant from the National Drug Intelligence Bureau and a member from Crown law also attended the meeting. The Crown Law representative provided legal advice on the issues considered by the EACD during its discussion of BZP.

3. DECLARATION OF CONFLICTS OF INTEREST

Dr Geoffrey Robinson advised the Committee that he is employed by for the Medicine Research Institute of New Zealand (MRINZ) and was involved with the study "The benzylpiperazine (BZP) / trifluoromethylphenylpiperazine (TFMPP) and alcohol safety survey" Thompson et al (2006), Medicine Research Institute of New Zealand (MRINZ).

Dr Helen Moriarty also advised that she was an external advisor for the study "Legal Party Pills and their use by young people: summary report of findings" Sheriden and Butler (2006), University of Auckland.

The Committee considered that Dr Moriarty posed no conflict of interest, and agreed that Dr Geoffrey Robinson should step down from the discussion on the MRINZ research project.

4. MINUTES OF THE EACD MEETINGS: 29 NOVEMBER 2006 & 15 FEBRUARY 2007

The minutes from the 29 November 2006 meeting were confirmed as a true and accurate record of that meeting. The minutes are currently on the National Drug Policy website.

The minutes from the 15 February 2007 meeting were confirmed as a true and accurate record of that meeting. The minutes are currently on the National Drug Policy website.

The Committee agreed to wait until the Minister has received advice before the Minutes of this meeting are placed on the website.

5. MATTERS ARISING

5.1 Report on Actions Arising from the 29 November 2006 EACD Meeting

Please refer to the minutes of the 29 November 2006 EACD meeting.

5.1.2 General Business – Indan(e)s and Aminoindan(e)s. Item 5.4

Issue: Secretariat to provide an assessment of indan(e)s and aminoindan(e)s for discussion at a future meeting.

Outcome: This topic is not on the current agenda as the National Drug Policy team's resources had been directed towards preparing the BZP update and additional documents. However, indan(e)s and aminoindan(e)s will be considered by the Committee under agenda item 9 when members review the list of substances scheduled to be discussed at future meeting dates.

5.1.3 General Business – Thalidomide. Item 5.5

Issues: Secretariat to prepare a paper for the Committee on Thalidomide for discussion at a future meeting.

Outcome: Thalidomide is to be discussed under agenda item 9.

5.1.4 BZP Update. Item 6

Issue: Implications of classifying BZP as a Class C1 controlled drug in the Misuse of Drugs Act 1975 on enforcement agencies and also the potential for increasing controls through the implementation of regulations.

Discussion: One Committee member expressed disappointment at not being able to attend the meeting held on 29 November 2006. He was surprised that the Committee felt the pressure to make a conclusion on partial data. Now that the EACD recommendation from the 29 November meeting has been made public, this member believed that it would be difficult for the Committee to re-consider their recommendation.

The Chair advised that the Committee will be reviewing the 29 November 2006 EACD recommendations at the current meeting, along with additional information. The Chair commented that the Committee will need to ensure that the process used to formulate the advice is robust.

The Committee agreed that there was no pressure to make a recommendation at the 29 November 2006 meeting, even thought there was plenty of public interest. The Committee also considered that there were a variety of issues that led the Committee to make their recommendations. Members were aware that the current status quo was not acceptable and therefore the main options were further regulation or classification as a controlled drug.

5.1.5 UK Criteria on Drug Scheduling. Item 9

Issue: It was agreed that the Secretariat would revise this paper for consideration at the 3 May 2007 EACD meeting to include information on the Australian Risk Management standards. The UK publication "Drug classification: making a hash of it?" would also be made available to EACD members.

Outcome: This will be considered under agenda item 8: Rational drug classification systems.

5.1.6 Zopiclone. Item 10

Issue: The Committee agreed to maintain a watching brief regarding any updates on the classification of zopiclone by the World Health Organization. It was agreed that no further action would be taken to recommend the classification of zopiclone under the Misuse of Drugs Act 1975 in New Zealand at this stage. The Chair was to inform the Minister and the Secretariat to write to manufacturers and inform them that no further action will be taken.

Outcome: Chair has informed Minister that the EACD advised that no further action is required. The Secretariat has advised manufacturers of this outcome.

5.1.7 Legal Status of 2C-T-7. Item 11

Issue: That the Committee recommend to the Minister that the definition of amphetamine analogues in Schedule 3, Part 7 of the Misuse of Drugs Act 1975 be amended to include "and/or alkylthio radicals" after "alkylamino radicals". It was agreed that the recommended amendment would be brought to the attention of the Minister for his direction on appropriate legislative action.

Outcome: This was brought to the attention of the Minister.

5.1.8 General Business – Gateway Theory. Item 12

Issue: It was agreed that the Secretariat would provide the EACD with a paper summarising evidence on the gateway theory, drawing in particular on work conducted in the UK.

Outcome: The Committee was interested in commissioning someone to undertake this piece of work for future EACD consideration. The Secretariat would investigate options.

5.1.9 Next Meeting. Item 13

Issue: Dr Robinson would provide a copy of his paper assessing alcohol against the EACD criteria for the information of EACD members at the next meeting.

Outcome: The paper will be considered by the Committee under agenda Item 7: Assessment of alcohol harm.

5.2 Report on Actions Arising from the 29 November 2006 EACD Meeting

5.2.1 Discussion on options for the presumption for supply of BZP and related piperazines. Item 4

Issue: The EACD would recommend five grams or 100 tablets, capsules, or other drug forms each containing some quantity of the drug as the level for the presumption for supply of BZP, phenylpiperazine and related substances in Schedule 5 of the Misuse of Drugs Act 1975.

Outcome: A summary of the EACD discussion has been approved by members and advice has been provided to the Associate Minister of Health.

6. BZP

Issue: The Committee was to review and determine what additional advice the EACD might want to give to the Minister in light of receiving further documents relating to BZP.

Background: On 4 December 2006, the EACD provided the Minister with their recommendation to classify BZP and related substances as Class C1 controlled drugs under the Misuse of Drugs Act 1975. The Minister announced this advice in December and a public consultation on this proposal closed on 23 March 2007.

Two of the key studies that informed the Committees discussion during the 29 November meeting have since been peer reviewed. There was also a review on the MRINZ study that was commissioned by the Social Tonics Association of New Zealand by two leading Australian commentators on drug issues. This review has been given to MRINZ for a response.

The Committee noted that the studies reviewed by the Committee used the term seizures to refer to anything from a small twitch to a grand seizure. Members agreed that this term was too broad and that some studies did not explain if the seizures were experienced because of withdrawal effects. However, it was also noted that the Gee paper had clearly documented three grand mal-type seizures.

Reference: Peer Review of the study entitled: *The benzylpiperazine (BZP) / trifluoromethylphenylpiperazine (TFMPP) and alcohol safety survey* by Thompson et al (2006) from the Medical Research Institute of New Zealand.

This study has been peer reviewed by Andrew Jull, University of Auckland, Associate Professor Michael Dawson, & Dr Alex Wodak, accessUTS, University of Technology, Sydney

Dr Robinsons stepped down from the discussion but remained present in the room to clarify issues as they arose.

Discussion: One Committee member noted that the MRINZ study was not a study designed to look at the side effects of BZP. Its purpose was to look at driving performance under an intoxicating dose of BZP with or without alcohol and the study results should be used to inform the primary goal of the study. With regards to side effects, the Committee member commented that the researchers were right to discontinue the study when they did, and that the Committee should take into consideration that in the members view, the side effects were most likely heightened as participants endured at least 6 hours of fasting and the substance was taken when it is not normally taken. The Committee noted a discrepancy that needed to be explained between the subjects' prior experiences when taking BZP in comparison to their experiences under the study's circumstances.

The Committee's interest in and response to this research was because the study was a randomised controlled trial, and the pattern of adverse events were seen entirely in the group that took BZP. The Committee assumed that the randomisation process was designed to minimise differences between the participant groups who did and did not consume BZP. The trial clearly showed a difference between the groups in the rates of adverse events. However, some Committee members agreed that the effect of an empty stomach and possibly caffeine withdrawal may have brought a heightened sensitivity and reaction to the ingestion of BZP.

The Committee noted that the level of side effects reported from the participants' previous use of BZP was consistent with other studies, with the most significant symptoms including a dry mouth, loss of appetite, nausea, and palpitations.

The SHORE study "Legal party pill use in New Zealand: Prevalence of use, availability, health harms and 'gateway effects' of benzylpiperazine (BZP) and trifluoromethylphenylpiperazine (TFMPP), and Auckland University study "Legal Party Pills and their use by young people: summary report of findings" showed users reporting similar effects at a high rate. The Committee noted that some of the participants who experienced side effects during the study reported that their symptoms were much worse than they had experienced previously and considered these symptoms quite debilitating.

Members discussed the small sample size of only 16 people in the intervention group. As a research cohort this is a small number and this issue was raised by one of the peer reviewers. Overall, the reviewer was very critical of the study and some of the issues raised in the review were unanswered by the authors of the study.

The Committee discussed the potential risk of harm from BZP, noting that people who take BZP tablets to get a 'quick buzz' will increase the amount of BZP taken in one session if they do not obtain the effect they were wanting with one dose. One member

noted that there has been a reduction in BZP-related hospital admissions and reports of decreased sales of BZP. Following the release of the EACD advice documenting safety issues.

One member, who hadn't been able to attend the November EACD meeting, expressed the opinion that the Committee placed too much emphasis on the finding of the MRINZ study. The members view was that stopping the trial early, because of the harm to the subjects, may have created an emotional overtone that influenced the Committee's decision.

Other members stated this study was not the catalyst for the decision nor did it dominate the thinking of the group, but it was a significant study that deserved an appropriate amount of consideration along with other evidence.

The Committee discussed the dosage given to subjects for the study and agreed that this was not an unreasonable amount, based on the doses recommended by the manufacturers and the user reports.

References: Theron et al (2007) "Benzylpiperazine based party pills' impact on the Auckland City hospital emergency Department Overdose database (2002-2004) compared with ecstasy (MDMA or methylenedioxymethamphetamine), gamma-hydroxybutyrate (GHB), amphetamines, cocaine, and alcohol".

Discussion: The Committee discussed this study and found it very interesting; it also received publicity when released. The description of cases and co-ingestants was slightly variable and there were slightly lower rates of co-ingestant use than shown in the SHORE study. The study reported only one BZP-related hospital admission, although this was not serious.

Committee members made the following observances. Firstly, BZP was deemed to be the main cause of hospital admissions, although no prior checks were done on the people that were administered before the study to know if the patients were heavy takers of BZP prior to being admitted. Secondly, it was unclear if the increase of presentations to the emergency department over the 3 years was because of the use of party pills or because clinicians' maybe more aware of BZP.. Thirdly, the study showed that the use of alcohol and amphetamine-related hospital admissions have been steady, which does not fit with the theory that BZP should be replacing amphetamines as a stimulant. Lastly, there was a lack of toxicology data in this study.

Reference: ESR Testing of "Torque"

Discussion: The Committee noted that "Torque" contained a relatively low level of BZP. It was also noted that there have been no deaths in New Zealand or internationally related to the use of BZP without other substances.

Reference: Consumer Link Survey (2007) Comparative risks of legal party pills, alcohol and illegal drugs.

Discussion: The Committee discussed the Consumer Link Survey commissioned by STANZ, which surveyed 200 young New Zealanders on a range of issues related to BZP. Members found it hard to place the findings without knowing full details of the methodology.

Reference: Analysis of Submissions

Discussion: The Committee noted that one of the key concerns raised from the analysis of submissions was the potential for BZP use to lead to permanent damage but the analysis does not provide any evidence that would support this hypothesis. There have been no reported BZP related deaths, or evidence of date rape. The Committee noted that BZP could lead to harm if taken with illicit drugs and/or alcohol, and poses a particular risk of harm if taken on an empty stomach or if the person who takes it has schizophrenia.

The Committee discussed the difficulty of ensuring the quality of BZP products. If regulations were strengthened, then the quality of the products would be assured, as long as monitoring was in place. Ironically, food has to be known to be safe before it is marketed and Members felt that there should also be an obligation on BZP importers to prove that the product does not pose a risk of harm to the public. Some submissions requested a ban on BZP sold in powder form.

The Committee discussed the use of BZP as an alternative to other illicit drugs, noting that the analysis of submissions showed that some users state that they use BZP instead of Methamphetamine. One Committee member noted that the majority of heavy illicit drug users would not contemplate using BZP as an alternative. With regards to moving to a stronger substance from BZP, the submissions suggested the shift more likely towards ecstasy rather than methamphetamine.

Some submitters considered that the EACD relied on research where the researchers could be viewed as having been compromised by the need to bid for funds or having a conflict of interest because of funding source.

A submission that requested a public representative on the EACD was discussed. Members noted that the public can comment on EACD discussion once the Minutes of meetings has been placed on the NDP website. Any change to the framework of the committee would have to go through the Minister as the EACD is a statutory body.

The Committee raised other matters for consideration to be placed in the advice to the Minister, these included;

- reports of an apparent reduction in use of BZP, reflected by the decline of number of cases presenting to Christchurch hospital, where there is a high degree of awareness of this substance.
- issue of the illegal drug market and the combination of substances in tablets and capsules appearing, although no evidence to date that legal party pill retailers are selling products with illegal substances in them.
- manufacturers seeking to market alternative products that aren't captured by a classification if a decision is made to classify BZP.

The Committee noted that Piperazine has been defined in the United Kingdom as a medicine. There has been an issue with importation into the UK, as it was not effectively controlled (although classified as a medicine), and UK suppliers were using New Zealand addresses to supply UK consumers ordering over the internet.

A Committee member noted that of greater interest than how the drug is accessed and abused by users is who the target user group is. None of the studies asked the user why

they took BZP. This member considered that once this question is answered further problems may be able to be solved.

The committee revisited the previous recommendations given to the Minister to see if any changes needed to be made now that further evidence was given. The Committee agreed that the conclusions from November meeting will stay substantially the same but some of the details should be changed. These changes were agreed, and are reflected in the recommendations.

Recommendation: The Committee noted that BZP creates dependence in very few people. Once taken, some users no longer wanted to take it again. As users usually take an overdose of substances such as BZP when they have their judgement impaired, usually by alcohol.

The Committee noted placing responsibility for proving safety on those supplying these substances in New Zealand is key to progress efforts to take a measured and evidence-based approach to drug classification and, importantly, reducing drug-related harm. This would require legislative change separate from any decision about scheduling BZP

Having discussed the new information available, the Committee reconsidered the recommendations contained in its December 2006 advice to the Minister. As in earlier discussions, there were different views among Committee members as to the potential risk of harm posed by BZP. Two Committee members considered that BZP poses a low risk of harm. A further Committee member considered that BZP poses a low-to-moderate risk of harm. Five Committee members present at this meeting held the view that BZP poses a moderate risk of harm. The two Committee members unable to attend this meeting and who attended the November 2006 meeting held the view at that time that BZP poses at least a moderate risk of harm.

7. Assessment of alcohol harm

Reference:
Should Ethanol be scheduled as a Class B1 drug under the Misuse of Drugs Act (1975) in New Zealand? D Sellman JD, Robinson GM, Beasley R, National Addiction Centre, University of Otago and Medical Research Institute of New Zealand.

Issue: This paper provided an analysis and discussion of the harms of ethanol by utilizing the nine criteria used by the EACD in considering new and potentially harmful substances. This paper was written to make people aware of ethanol and its harms.

Discussion: The paper has been submitted for publication.

Outcome: Paper was noted by the Committee

As the meeting ran over time Items 8 and 9 will be discussed at the next meeting, the Chair thanked members for their attendance and closed the meeting.

10: Dates of Future EACD Meetings

The date for the next EACD meeting was confirmed to be held on Thursday 28 June 07.