

4 December 2006

Hon Jim Anderton MP
Associate Minister of Health
Parliament Buildings
WELLINGTON

Dear Minister

Further EACD Advice on Benzylpiperazine (BZP) and related substances

The EACD met on 29 November 2006 and considered a range of new information on BZP. All members of the EACD were present, with the exception of Professor Doug Sellman. I have spoken separately with Professor Sellman to elicit his views and have included his specific comments.

The Committee wishes to express its thanks for the strong support you have provided for the approach recommended in its earlier advice on BZP in 2004. The addition of a Restricted Substances Schedule to the Misuse of Drugs Act 1975 (MODA) is an important achievement. The programme of research on BZP that has been undertaken has allowed New Zealand to take a strongly evidence-based approach to dealing with BZP. New Zealand has now built a significant body of research on BZP, which will inform both national and international responses.

This further advice is based firmly on the research and other evidence that has accumulated. This approach is consistent with New Zealand's National Drug Policy and has put in place mechanisms that will assist New Zealand to address emerging drugs where there is uncertainty about the potential harms.

The Ministry of Health assembled a comprehensive package of relevant information on BZP for the EACD meeting, and your office has been provided with a copy of this. The following documents were included.

- An overview paper compiled by the National Drug Policy team summarising key findings of each of the papers
- A report titled "Legal party pill use in New Zealand: Prevalence of use, availability, health harms and 'gateway effects' of Benzylpiperazine (BZP) and Trifluoromethylphenylpiperazine (TFMPP)" by Wilkins et al at the Centre for Social and Health Outcomes Research and Evaluation (SHORE), Massey University, published in July this year.
- A recently-completed report by Sheridan and Butler from the University of Auckland School of Pharmacy titled "Legal party pills and their use by young people: summary report of findings".
- A letter dated 24 November 2006 from the National Poisons Centre at the University of Otago summarising preliminary results from their research into cases of poisoning due to piperazine-based party drugs (PBPD) in New Zealand.

- A confidential draft report dated 24 November 2006 titled “The benzylpiperazine (BZP) / trifluoromethylphenylpiperazine (TFMPP) and alcohol safety survey by Thompson et al at the Medical Research Institute of New Zealand.
- A New Zealand Medical Journal Paper “Toxic effects of BZP-based herbal party pills in human: a prospective study in Christchurch, New Zealand” by Gee et al published in December 2005.
- A report from the Levin Coroner on an inquest completed on 23 May 2005.
- An interim report dated 28 November 2006 from ESR providing findings from testing of the ingredients of 8 popular brands of party pills.
- A confidential draft report titled “Patterns of use of legal piperazine party pills containing Benzylpiperazine (BZP) and Trifluoromethylphenylpiperazine (TFMPP) and adverse effects in a population sample in New Zealand” by Wilkins et al at the Centre for Social and Health Outcomes Research and Evaluation (SHORE), Massey University.
- An October 2006 research report titled “BZP users attending Christchurch Emergency Department” by Gee et al at Christchurch Hospital.
- An email of 28 November 2006 from Bruce Russell at the School of Pharmacy, University of Auckland, briefly summarising their research on BZP and TFMPP.
- An email dated 23 November 2006 from Matt Bowden, Chair of the Social Tonics Association of New Zealand
- A submission on Party Pills dated 20 October 2006 from Jacqui Dean, MP for Otago.

The EACD considered each of the documents in turn and, in the case of the research studies, discussed the findings. A summary of the Committee’s key findings will be included in the final minutes of the 29 November 2006 meeting.

Following this discussion, the Committee then considered BZP against each of the criteria we are required to consider under Section 4B of the MODA 1975.

a. the likelihood or evidence of drug abuse, including such matters as the prevalence of the drug, levels of consumption, drug seizures trends, and the potential appeal to vulnerable populations.

- BZP is widely available, accessible and actively marketed.
- BZP is widely used: around 20% of people aged 13 to 45 have ever used party pills containing BZP, including nearly 50% of males aged 20 to 24. Around 15% of people aged 13 to 45 admit to using party pills in the past year.
- BZP is almost invariably used with alcohol.
- BZP is also included in some preparations intended for daily use such as dieting agents.
- Public perception is that party pills are being targeted to individuals under-18 year of age. Evidence also shows that under-18 year olds are using BZP.

- Drug seizures are not relevant in this case, although the EACD is aware that Australia jurisdictions are seizing BZP that has been ordered over the internet and shipped from New Zealand.

b. The specific effects of the drug, including pharmacological, psychoactive, and toxicological effects

- BZP is an amphetamine-like substance with significant stimulant effects. The EACD is of the opinion that the current evidence suggests that BZP's potency is approximately one tenth that of the equivalent weight of dexamphetamine.
- Compared with other substances current controlled under the MODA, the pharmacological, psychoactive and toxicological profile of BZP indicates that the risk associated with BZP use is lower than that of methamphetamine, and broadly similar to that of ephedrine.
- There are perceived beneficial effects (e.g. wakefulness and increased sociability).
- Adverse effects are common, in particular insomnia, headaches, flushes, nausea and vomiting, and some of these may be a result of piperazines other than BZP e.g. TFMPP. Seizures have been reported.
- Studies show a relatively slow onset of effect, which can lead users to take repeat or high doses to gain a more rapid effect. BZP is excreted relatively slowly, which produces a prolonged duration of effect that possibly contributes to the pronounced "come down" effect.
- The effects of chronic use are unknown.
- A controlled trial demonstrated frequent and severe adverse effects from BZP and TFMPP.
- There is potential for severe toxicity in some individuals, which has been reported after relatively low doses.
- BZP is often taken with alcohol and other drugs, making toxicological effects difficult to predict.

c. The risks, if any, to public health

- Although there are no formal reports, there is potential for harm to others e.g. the effects of rebound fatigue or acute intoxication on driving performance or operation of machinery
- There is concern that BZP use has been 'normalised', potentially creating or contributing to an increased risk of a culture of drug use that may encourage individuals to participate in other substance use.
- It is possible that some users who would otherwise use more harmful drugs especially methamphetamine are using BZP as a legal (and safer) alternative.
- As with alcohol and other psychoactive drugs, there is the potential to affect neurodevelopment in adolescents.
- There is a suggestion of links with New Zealand's culture of risky alcohol consumption

- Evidence shows very low levels of intravenous BZP use presently, hence there is a low risk of blood-borne communicable diseases associated with its use. The availability of raw BZP powder and the potential to extract BZP powder from capsules creates a potential risk of increased intravenous use.
- There is a public perception that the legal status implies that BZP has been through a robust regulatory process and is thus considered 'safe', even though the products are not subject to any form of safety or quality review before they enter the market.
- There is no evidence of aggressive behaviour, sexual assault or date rape type behaviours.
- There have been no recorded deaths solely as a result of BZP use. Use of BZP is associated with a high rate of adverse effects: severe adverse effects occur unpredictably and have been reported at relatively low doses.

d. The therapeutic value of the drug, if any

- No evidence in any robust scientific studies to date has shown that BZP has any therapeutic use in humans.
- At least one product containing BZP is actively marketed in pharmacies as an aid to weight loss. Some anecdotal evidence of contribution to weight loss, which would fit with its status as a stimulant.

e. The potential for use of the drug to cause death

- No evidence to date of any deaths in New Zealand or internationally caused solely by BZP consumption.
- However, toxic effects, especially BZP-related seizures that have been described even at relatively low doses, have the potential to lead to death.
- The potential to cause death is increased from the way in which BZP is frequently used with other substances (e.g. alcohol) and in high doses.

f. The ability of the drug to create physical or psychological dependence

- Some evidence suggests that BZP has the ability to create dependence.

g. The international classification and experience of the drug in other jurisdictions

- BZP is not classified in any international drugs treaties.
- The United Nations Office on Drugs and Crime International Narcotics Control Board has previously written to New Zealand requesting information on our experience with BZP and intentions regarding possible controls.

- Australia and the USA have made BZP illicit, although on the basis of little or no experience with the drug.
- There is a growing international perception of New Zealand being a primary BZP supplier, which has the potential to impact on New Zealand's international reputation.

h. Any other matters for consideration that the Minister may consider relevant

- A key concern is the widespread availability of BZP with few restrictions on and how BZP can be sold and by whom.
- Most party pills also include TFMPP, which may be responsible for some of the adverse effects. Other piperazines, about which there is no safety information, are now being included in some party pills.
- A possible mechanism for reducing demand and funding regulatory and enforcement activities could be subjecting party pills to taxation other than GST e.g. an excise tax.
- Should BZP be made illegal, this may discourage people who continue to use it from seeking medical attention if they experience adverse effects.
- A key policy issue that needs an explicit decision is whether New Zealand wishes to have a legal market for psychoactive drugs.

Recommendations

The Committee recognises that there are potential advantages in retaining BZP as a Restricted Substance, as the Misuse of Drugs Amendment Act 2005 has provisions allowing a range of restrictions to be put in place. Likewise, there is no guarantee that scheduling a substance as a controlled substance under the MODA reduces the availability or potential risk of harm from a drug.

In theory, a regime could be put in place to control, *inter alia*, the availability, advertising and supply of BZP, which would address some of the concerns about its current availability and use. However, in practice this will require the establishment of a significant administrative and enforcement capacity, for example as there is for pharmaceuticals and for the legal drugs tobacco and alcohol.

The Committee considered these issues carefully. However, based on its careful assessment, it was the view of the EACD that BZP poses a moderate risk of harm. The studies carried out to date have documented real harm and there is still no information about the possible long-term consequences of BZP use. In addition, and importantly, BZP has no proven therapeutic use in humans. The Committee was particularly concerned about the current wide availability and supply of BZP in locations that children and young people can easily access.

Therefore, the Committee recommends the following:

- 1. that BZP be classified under Schedule 3 Part 1 (Class C1) of the Misuse of Drugs Act 1975**

2. **that the classification as a Class C1 drug covers all known analogues and derivatives of benzylpiperazine and phenylpiperazine that have no known therapeutic use**
3. **that BZP be removed from Schedule 4 of the Misuse of Drugs Amendment Act 2005 in order that it no longer be a Restricted Substance**
4. **that work continue to further develop the regulatory framework and enforcement capacity that would support the Restricted Substances provisions of the Misuse of Drugs Amendment Act 2005.**

While scheduling BZP as a controlled substance under the MODA will lead to the removal of party pills from the legal market, the change in legal status is no guarantee that the availability and use of BZP will decrease. However, the Committee points to the recent experience with GHB (Fantasy), where scheduling of the substance has led to a significant decrease in its use. In addition, the widely-described negative effects of BZP use (such as insomnia, headaches and nausea) suggest that this is not likely to be a drug that people will actively seek if it is less available, more expensive and carries risks associated with illicit status.

The Committee wishes to emphasise the importance of the fourth recommendation, as new synthetic psychoactive substances are emerging at an increasing rate and the provisions of the Misuse of Drugs Amendment Act 2005 allow tight restrictions to be placed on these drugs. While it is the EACD's view that the research has now demonstrated that BZP does pose a moderate risk of harm, newer substances may be shown to pose a low risk of harm but still be worthy of restrictions. The Committee's view is that the implementation of restrictions should place the burden of proof on the person supplying the substance to demonstrate the safety of a new psychoactive substance.

The Committee believes that the Government needs to explicitly consider whether it wants to put in place such arrangements to deal with non-therapeutic psychoactive substances that do genuinely pose a low risk of harm to health. In the Committee's view, it is important that additional regulations supporting the provisions of the Misuse of Drugs Amendment Act 2005 are adequately supported. For example, a licensing regime might be required, which will require administration and enforcement capacity.

Yours sincerely

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