

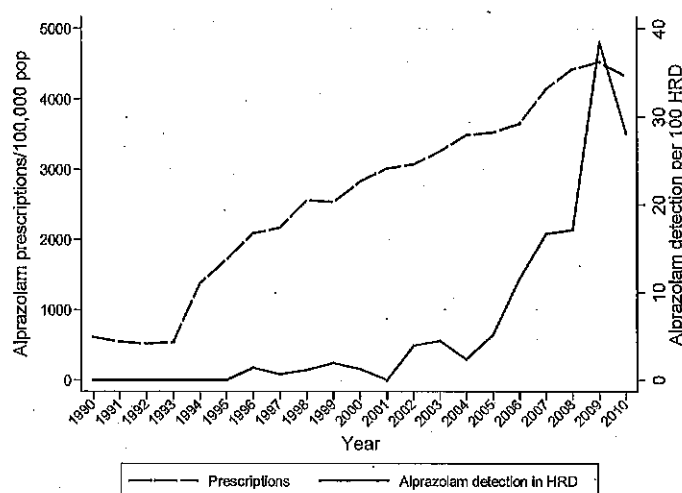
PROBLEMS WITH BENZODIAZEPINES AND ALPRAZOLAM

Contribution to combined drug toxicity deaths.

There is a high prevalence of detection of benzodiazepines in heroin-related deaths. In Victoria, benzodiazepines were found in 55% of all deaths involving heroin reported to the Victorian Coroner in 2004-2008¹¹.

A recent examination of detection of different benzodiazepines in heroin-related deaths in Victoria found an increasing trend of detection of alprazolam in these deaths¹². Alprazolam detection increased from 5.2% of deaths in 2005 to 35.3% of deaths in 2009. The authors concluded that this increase may be a consequence of increasing misuse of this benzodiazepine, and increased prescribing of the high dose 2mg form.

Figure: Number of alprazolam prescriptions and detection of alprazolam in heroin-related deaths: Victoria, 1990-2010.



There is also a high prevalence of detection of benzodiazepines in deaths involving oxycodone and other prescription opioids. Benzodiazepines were detected in 68.6% of oxycodone toxicity deaths in New South Wales in the years 1999-2008¹³.

A US review of poisoning deaths involving oxycodone describes that benzodiazepines were the most frequently detected CNS depressant drugs (56.3%) other than oxycodone in all deaths involving multiple drugs¹⁴.

Contribution to non-fatal drug toxicity overdose and emergencies.

Benzodiazepines, and alprazolam are common drugs in overdose incidents leading to hospital and emergency department admissions.

A study of poisoning admissions examined by a regional toxicology service in New South Wales (1997-2002)¹⁵ concluded that:

¹¹ Woods J, Gerostamoulos D, Drummer OH. Heroin deaths in Victoria 2007/2008. Victorian Institute of Forensic Medicine, Department of Forensic Medicine, Monash University. 2009.

¹² Rintoul A et al. Recent increase in detection of alprazolam in Victorian heroin-related deaths. Med J Aust 2013 (In press).

¹³ Darke S et al. Toxicology and characteristics of fatal oxycodone toxicity cases in New South Wales, Australia, 1999-2008. J Forensic Sci 2011;56:690-3.

¹⁴ Cone EJ et al. Oxycodone involvement in drug abuse deaths: A DAWN-based classification scheme applied to an oxycodone post-mortem database containing over 1000 cases. J Analytic Toxicol 2003;27:57-

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"Alprazolam was significantly more toxic than other benzodiazepines. The increased prescription of alprazolam to groups with an increased risk of deliberate self poisoning is concerning and needs review."

United States. In 2009, slightly over 120 million visits were made to Emergency Departments (EDs) in general-purpose hospitals in the United States, and the Drug Abuse Warning Network (DAWN) estimates that at least 4.5 million of these visits were drug related¹⁶. Drug-related ED visits have increased by over 80 percent since 2004. This increase primarily reflects greater numbers of medical emergencies associated with adverse reactions, accidental drug ingestions, and misuse or abuse of prescription drugs and over-the-counter medications.

About 2.1 million ED visits resulted from medical emergencies involving drug misuse or abuse, the equivalent of 674.4 ED visits per year per 100,000 population. Drugs for insomnia and anxiety were involved in 24.7 percent of visits where drugs and alcohol were taken together, with the largest part of that being benzodiazepines (anti-anxiety drugs; 21.0%).

Pain relievers were the most common type of drugs reported in the nonmedical use category of ED visits (47.8%). Drugs used to treat anxiety and insomnia were also seen frequently (33.6%) in visits related to nonmedical use of pharmaceuticals. Benzodiazepines were involved in 29.0 percent of such ED visits, with alprazolam (e.g., Xanax®), indicated in 10.4 percent of such visits.

At 38.1 percent, pain relievers were the most commonly involved type of drug in drug-related suicide attempts. Benzodiazepines followed pain relievers at 28.7 percent, with alprazolam and clonazepam (e.g., Klonopin®) accounting for 11.7 percent and 8.1 percent of these visits, respectively.

The number of drug-related suicide attempts has remained stable from 2004 to 2009. However, a significant rise was observed in the involvement of two pain relievers—hydrocodone and oxycodone—and three anti-anxiety drugs—alprazolam, clonazepam, and zolpidem (e.g., Ambien®).

Among individuals attending EDs seeking detoxification services, the types of drugs involved, cocaine was observed in 29.2 percent of visits, heroin in 28.4 percent, marijuana in 18.3 percent, and stimulants in 5.4 percent. Among pharmaceuticals, narcotic pain relievers were observed in 38.2 percent of visits, including oxycodone at 22.2 percent. Benzodiazepines were observed in 23.7 percent of visits, with alprazolam at 13.5 percent.

Victoria, Australia. A 2004 study of all medication overdose presentations to an inner-city Melbourne hospital found that two benzodiazepines, diazepam and alprazolam, appear to be over-represented in the overdose data relevant to their population levels of prescription¹⁷.

When the number of overdose events treated involving the different benzodiazepines is related to a more accurate description of the number of prescriptions provided to Victoria in 2004, it can be seen that alprazolam is the most over-represented in terms of the number of presentation per million prescriptions (Victorian data calculated from Australian information supplied by the PBAC Drug Utilisation Subcommittee). See table.

¹⁵ Isbister GK et al. Alprazolam is relatively more toxic than other benzodiazepines in overdose. *Brit J Clin Pharmacol* 2004;58:88-95.

¹⁶ Substance Abuse and Mental Health Services Administration, Drug Abuse Warning Network, 2009: National Estimates of Drug-Related Emergency Department Visits. HHS Publication No. (SMA) 11-4659, DAWN Series D-35. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011. Available from: <http://www.samhsa.gov/data/2k11/DAWN/2k9DAWNED/HTML/DAWN2k9ED.htm>

¹⁷ Buykx P et al. Medications used in overdose and how they are acquired – an investigation of cases attending an inner Melbourne emergency department. *Aust NZ J Public Health* 2010;34:401-4.

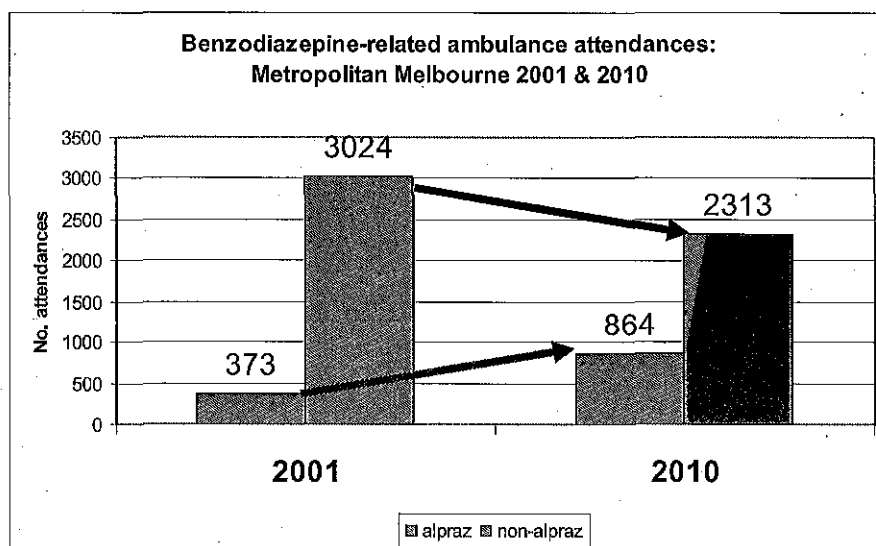
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benzodiazepine	No. cases	scripts 2004	cases per m scripts
diazepam	46	568,787	80.9
alprazolam	26	174,880	148.7
temazepam	20	767,036	26.1

Another Victorian study examining the antecedent circumstances of non-fatal heroin overdoses found that there was a 28-fold greater risk of overdose if benzodiazepines had been used in the preceding 12 hours¹⁸.

Ambulance data from Melbourne.

Best et al reported an analysis of ambulance attendance records in Melbourne to determine trends in involvement of benzodiazepines, and particularly alprazolam in ambulance attendances between 2001 and 2010¹⁹. They reported a small decline in general number of benzodiazepine attendances, but that alprazolam-related attendances had increased by 132%, and that furthermore taking prescription numbers into account, noted a two-fold increase in rates, and rates for alprazolam arising to double that of diazepam in 2010.



Misuse by people who inject drugs (PWID).

The National Drug and Alcohol Research Centre auspices the Illicit Drug Reporting System, a continuing study of drug use and harm by people who inject drugs (PWID). The study interviews approximately 100 subjects from each Australian jurisdiction.

In Victoria 71% of the sample reported recent use of benzodiazepines, although a much smaller proportion reported recent injection (2%)²⁰. Sixty-nine percent of the sample reported recent use of illicit alprazolam, the highest single report in the Victorian IDRS of illicit use of a prescribed medication.

¹⁸ Dietze P et al. Transient change in behaviour lead to heroin overdose: results from a case-crossover study of non-fatal overdose. *Addiction* 2005;100:636-42

¹⁹ Best D et al. Alprazolam and wider benzodiazepine misuse in Australia – sources of supply and evidence of harms. *Aust NZ J Psychiatry* 2012;

²⁰ Kirwan A et al. Drug Trends 2011. Findings from the Illicit Drugs Reporting System. Macfarlane Burnet Institute for Medical Research and Public Health and Turning Point Alcohol and Drug Centre Australian drug Trends Series No 76, Melbourne 2012

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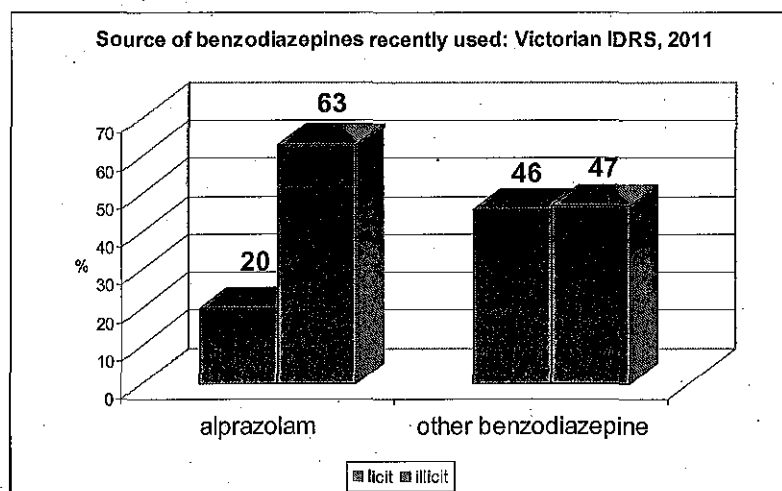
The 2011 survey focused on the drug or drugs KE perceived to be 'most problematic' at the time of interview. A total of 17 responses were elicited in this area of questioning. The drugs named as most problematic by KE were most commonly prescription opiates (n=8), alprazolam (Xanax, a short-acting benzodiazepine) (n=3) and antipsychotics (n=3).

It can be seen from the table below that for Victorian IDRS subjects:

- only 20% of subjects using alprazolam in the last 6 months obtained it on prescription, compared to 46% of other benzodiazepine users
- a higher proportion of subjects using alprazolam in the last 6 months obtained them illicitly without a prescription (63%) than subjects using other benzodiazepines (47%)
- alprazolam injection in the last 6 months was more common (7%) than injection of other benzodiazepines (2%) and alprazolam injected was exclusively obtained illicitly (without prescription).

	Ever used %	Ever injected %	Used last 6 months %	Injected last 6 months %
Alprazolam				
Alpraz prescribed	31	3	20	0
Alpraz not prescribed	81	11	63	7
Any form	88	14	69	7
Other benzodiazepines				
Prescribed	75	7	46	1
Not prescribed	73	9	47	1
Any form	92	12	71	2

Alprazolam was considerably less likely to be prescribed directly to those using it, and more likely to be obtained through illicit sources (not prescribed to the individual) than other benzodiazepines.



A study of use of alprazolam among Victorian Illicit Drug Reporting System over the 3 years 2008-10 comparing IDRS subjects using alprazolam with those using other benzodiazepines, found that the significant differences were that they were more likely to be currently prescribed opioid substitution treatment (OST) (66.7% vs 49.8%), mainly using illicit benzodiazepines (59.5% vs 29.6%), more likely to have recently injected a benzodiazepine (14.8% vs 4.9%), and more likely to have sold drugs for cash (42.0% vs 26.9%)²¹. The authors also reported that Needle and Syringe Program staff accessed through the IDRS in Melbourne had reported increasing antisocial behaviour, particularly opportunistic criminal activity, believed to be associated with alprazolam use.

²¹ Horyniak D et al. The use of alprazolam by people who inject drugs in Melbourne, Australia. Drug and Alcohol Rev 2011;

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Reports by Australian IDRS subjects of trends in their recent use of alprazolam and of the most common benzodiazepine injected show increasing trends of use and injection of alprazolam in the period 2003 to 2011.

Year	% recent use alprazolam	Most common injected
2003	3	diazepam
2004	4	diazepam
2005	5	diazepam
2006	6	diazepam
2007	11	alprazolam
2008	14	alprazolam
2009	17	alprazolam
2010	21	alprazolam
2011	46	alprazolam

Benzodiazepine use causes particular problems for opioid dependent people.

A number of papers describe that benzodiazepine use by injecting drugs users is associated with poorer social functioning, greater levels of polydrug use, and increased risk of HIV risk-taking behaviour such as needle sharing, borrowing or sharing injection equipment, increased frequency of injection, increased injection of heroin and methamphetamines than other PWID^{22 23}. Benzodiazepine users in methadone treatment also exhibited higher levels of psychopathology and social dysfunction than other methadone maintenance clients.

Another study examined the health service utilisation and benzodiazepine use among heroin users recruited through the Australian Treatment Outcome Study (ATOS)²⁴. Benzodiazepine users had more GP and psychiatrist visits, were more likely to have had an ambulance attendance and had significantly more dispensed prescriptions.

Benzodiazepine co-dependence with opioid dependence exacerbates the opiate withdrawal syndrome. In one study, Co-dependent patients had significantly more severe opiate withdrawal symptoms²⁵

Benzodiazepine use by patients in methadone treatment causes significant problems for many patients. Those who used benzodiazepines experienced more polydrug use, and higher self-rated psychopathology and psychological distress scores²⁶.

²² Darke S et al. Benzodiazepine use and HIV risk-taking behaviour among injecting drug users. *Drug Alcohol Depend* 1992;31:31-6.

²³ Darke S et al. Drug use, HIV risk-taking and psychosocial correlates of benzodiazepine use among methadone maintenance clients. *Drug Alcohol Depend* 1993;34:67-70.

²⁴ Darke S, Ross J et al. Health service utilization and benzodiazepine use among heroin users: findings from the Australian Treatment Outcome Study (ATOS). *Addiction* 2003;98:1129-35.

²⁵ De Wit C et al. Benzodiazepine co-dependence exacerbates the opiate withdrawal syndrome. *Drug Alcohol Depend* 2004;75:31-5.

²⁶ Bleich A et al. Benzodiazepine abuse in a methadone maintenance treatment clinic in Israel: characteristics and a pharmacotherapeutic approach. *Isr J Psychiatry Relat Sci* 2002;39:104-12.

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Co-ingestion of benzodiazepines with methadone augments the physiological and subjective opioid effects of methadone²⁷. Use by methadone patients increased some subjective opioid effects, and this may be related to the relatively greater use and abuse of benzodiazepines in this population.

Misuse of benzodiazepines amongst drug treatment clients.

Australia. Nielsen et al examined the pharmaceutical drug misuse of clients admitted to drug treatment in four States in Australia (Victoria, Western Australia, Tasmania and Queensland)²⁸.

Pharmaceutical opioids and benzodiazepines were identified as the most commonly misused prescription drugs, with a broad range of treatment presentations, such as dependence developing from medical use and pharmaceutical drugs being used as a substitute for illicit drugs. Key Experts also reported a group of pharmaceutical misusers who did not present for treatment at traditional alcohol and drug treatment services, with these primary pharmaceutical misusers being thought to be a "hidden population".

Diazepam and alprazolam were the most common benzodiazepines reported. A range of harms (including dependence, withdrawal, effects on memory and a range of injecting related harms) were reported, although only a minority of these harms resulted in a medical intervention. Among the benzodiazepines, alprazolam was particularly associated with the experience of harmful outcomes.

Alprazolam appeared to be more problematic than other benzodiazepines with disproportionate harms associated with alprazolam use.

While data indicates that diazepam was the main benzodiazepine used by the sample, a large proportion of individuals reporting seizures (55%), traffic accidents (50%), and crime (30%), while under the influence of benzodiazepines, identified that alprazolam was the main benzodiazepine involved (ahead of diazepam and other benzodiazepines). As such, there was a disproportionately high level of harm associated with alprazolam use.

It appears that rates of harms are broadly comparable with pharmaceutical opioids and benzodiazepines, though effects on memory and being arrested while intoxicated appeared more common with benzodiazepines. A disproportionate amount of harm was reported with the benzodiazepine alprazolam.

The findings of this study, in agreement with the recommendation in the DCPC report (Drugs and Crime Prevention Committee, 2007) was that alprazolam was more problematic than other benzodiazepines. The finding of disproportionate harms associated with alprazolam use is significant. Monitoring to establish the extent of alprazolam misuse and related harms is warranted to inform consideration of whether a regulatory response is required.

The authors referred to a number of journal articles describing problems with alprazolam^{29 30 31 32}.

²⁷ Preston KL, Griffiths RR et al. Diazepam and methadone interactions in methadone maintenance. *Clin Pharmacol Ther* 1984;36:534-41

²⁸ Nielsen S, Bruno R, Carruthers S, Fischer J, Lintzeris N, Stoové M. INVESTIGATION OF PHARMACEUTICAL MISUSE AMONGST DRUG TREATMENT CLIENTS. FINAL REPORT 2008. Turning Point Alcohol and Drug Centre, Melbourne 2008.

²⁹ French AP (1989) Dangerously aggressive behavior as a side effect of alprazolam. *The American Journal of Psychiatry* 146:276.

³⁰ Rudorfer MV, Osman OT and Potter WZ (1989) Alprazolam and aggression. *The American Journal of Psychiatry* 146:949-950.

³¹ Verster JC and Volkerts ER (2004) Clinical Pharmacology, Clinical Efficacy, and Behavioral Toxicity of Alprazolam: A Review of the Literature. *CNS Drug Reviews* 10:45-76.

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United States.

A recent paper from the United States reported on the number of substance abuse treatment admissions reporting both benzodiazepines and narcotic pain reliever abuse in the period 2000-2010, and noted that there was a 569.7% increase in these admissions over this period, while the number of other admissions had decreased by 9.6%³³. The average age of benzodiazepine and narcotic pain reliever combination admissions was 31.2 years, and 66.9% were aged 18-34 years, whereas 43.7% of other admissions were in this age bracket, and a higher proportion of other admissions were older. A higher proportion of these admissions were female than for other admissions.

In 2010, 48.2% reported primary narcotic pain reliever abuse and secondary benzodiazepine abuse, while 9.9% reported primary benzodiazepine abuse and secondary narcotic pain reliever abuse. The remaining 41.7% reported some other primary substance abuse with benzodiazepines and narcotic pain reliever as secondary or tertiary drugs of abuse.

More than one-third of the admissions reported initiating narcotic pain relievers first (34.1%); more than one quarter reported initiating benzodiazepines first (27.1%), and the remainder (38.7%) reported that the two drugs were initiated in the same year.

In the month prior to treatment admission for combination benzodiazepine and narcotic pain reliever abuse, 61.2% reported daily use of any substance compared with 34.6% of other admissions.

Treatment admissions differed in this group, with benzodiazepine and narcotic pain reliever combination admissions were more likely than other admissions to self-refer to treatment (35.7% vs 30.5%), and less likely to be referred through the criminal justice system (20.3% vs 39.8%), suggesting that they were a different cohort.

Benzodiazepine and narcotic pain reliever combination admissions were more likely to report a co-occurring psychiatric disorder than other admissions (45.7% vs 27.8%).

The high proportion of benzodiazepine and narcotic pain reliever admissions reporting daily use suggests behavioural patterns that may be difficult to change, and the individuals involved need to be prepared for the severe withdrawal effects from both drugs, particularly since benzodiazepines may worsen the withdrawal effects of narcotic pain relievers.

Misuse, diversion and trafficking.

A US study examining how drug dealers acquire their inventory of prescription drugs, and which types they most commonly sell, found that the type of medication most commonly sold by dealers was prescription opioid analgesics, and to a lesser extent benzodiazepines such as alprazolam.

"Xanax pills (2 mg), known as 'zanny bars' or 'footballs', were also a fairly common medication that dealers reported selling, but this comprised a much lower proportion of their overall sales in comparison to opioids."

The Drugs and Crime Prevention Committee of the Victorian Parliament recently conducted an *Inquiry into The Misuse/Abuse Of Benzodiazepines And Other Forms Of Pharmaceutical Drugs in Victoria Melbourne*³⁴.

³² Verster JC, Volkerts ER and Verbaten MN (2002) Effects of alprazolam on driving ability, memory functioning and psychomotor performance: a randomized, placebo-controlled study. *Neuropsychopharmacology* 27:260-269.

³³ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (December 13, 2012). *The TEDS Report: Admissions Reporting Benzodiazepine and Narcotic Pain Reliever Abuse at Treatment Entry*. Rockville, MD.

³⁴ Drugs and Crime Prevention Committee. *Inquiry into the misuse/abuse of benzodiazepines and other forms of pharmaceutical drugs in Victoria Melbourne*: Parliament of Victoria 2007.

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Because of the evidence they received about the particular concern about alprazolam relative to other benzodiazepines, the committee included a special note on alprazolam (See Appendix 1).

Witnesses reported evidence that alprazolam can be particularly dangerous when used for recreational purposes or administered the wrong way. Experts reported the highly addictive qualities and difficulties associated with withdrawing from the drug. Also that it was becoming favoured as a drug for misuse. There was also concern that alprazolam featured more prominently in crime-related activity. Others reported that alprazolam tablets were being trafficked on the street, used as a 'date rape' drug, or used to facilitate robberies.

The note included reference to a submission from the Victorian Interhospital Addiction Liaison Association (VAILA) that alprazolam was one of the most widely abused benzodiazepines, and that management of withdrawal was particularly difficult. VAILA recommended that this benzodiazepine be rescheduled to Schedule 8.

The note went on to describe action taken in Tasmania to misuse of alprazolam.

Another report by the Drugs and Crime Prevention Committee of the Victorian Parliament³⁵ *Inquiry into the Impact of Drug-related Offending on Female Prisoner Numbers - Interim Report*. noted a submission from support organisations for women released from prison reporting that misuse of prescription medications contributed to offending and imprisonment. Women who had been in 'the system' felt that 'pills' presented a greater risk for offending than heroin. The Committee was told that the legal and illegal use of Xanax and benzodiazepines was an issue. Moreover, anecdotal reports alleged there are certain health professionals allegedly well known to prescribe high doses of these and other highly addictive prescription drugs to dependent women on request. The Committee was also told that many clients who had been in prison or police custody in the past six months reported that their offences had not been pre-planned and that they could not recollect their actions as a result of 'Xanax misuse blackouts'

Trafficking: Street price of alprazolam tablets in Melbourne.

Submissions to the two Drugs and Crime Prevention Committees inquiries described above report black market prices of alprazolam:

A submission to the *Inquiry into The Misuse/Abuse Of Benzodiazepines And Other Forms Of Pharmaceutical Drugs in Victoria Melbourne* from the Pharmacy Board of Victoria reported that it was not uncommon for Xanax tablets (100) to be prescribed and dispensed as private prescriptions and then on-sold on the street at \$5.00 per tablet.

A submission to the *Inquiry into the Impact of Drug-related Offending on Female Prisoner Numbers - Interim Report* described that "It was further reported that specific areas of Melbourne are well known for the sale and distribution of illegal benzodiazepines, including Richmond and Footscray where it is allegedly possible to purchase three Xanax off the street for \$10."

The Tasmania IDRS has followed prices paid for alprazolam on the street in that State for several years³⁶.

In the 2011 study, the median last purchase price for a 2mg alprazolam tablet was \$12.50 (range \$8-20, n=26). The median purchase price has steadily increased from \$5 in 2006 following the regulatory changes in that State. Similarly, the range of prices paid by

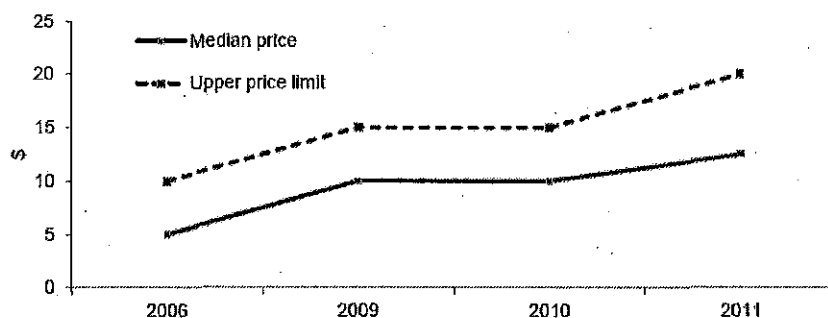
³⁵ Drugs and Crime Prevention Committee. *Inquiry into the Impact of Drug-related Offending on Female Prisoner Numbers - Interim Report*. Melbourne: Parliament of Victoria, 2010

³⁶ De Graaf B et al. *Tasmanian Drug Trends 2011. Findings from the Illicit Drug reporting System*. Australian Drug Trends Series No 77. School of Psychology, University of Tasmania. 2012.

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participants has increased: in 2006, \$10 was the maximum price paid for a 2mg tablet, in 2011 this increased to \$20,

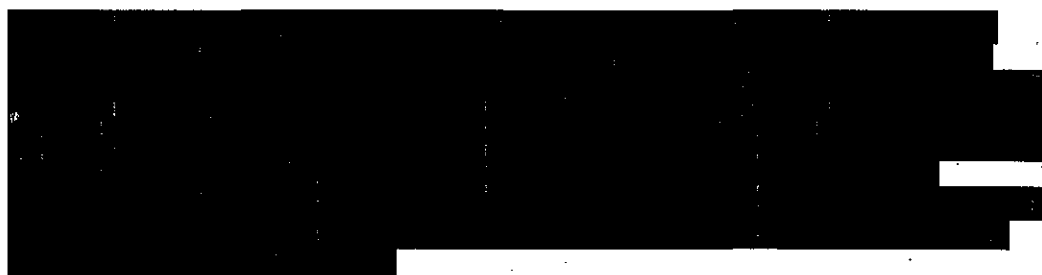
Figure 65: Median and upper limit of prices paid for 2mg alprazolam, 2006-2011*



Source: IDRS PWID interviews

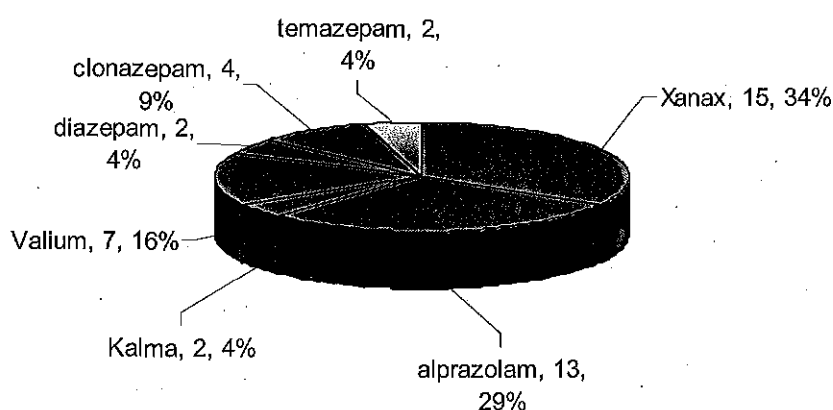
*This data was not collected in the 2007-2008 surveys

In 2010 the Chief Health Officer of the Northern Territory informed general practitioners and psychiatrists in the Territory about problems of limb ischaemia from the injection of alprazolam, and other problems (See Appendix 4). The letter included a reference to street price in the Northern Territory and Adelaide: the lucrative street price of a single 2 mg tablet of alprazolam in Darwin and Alice Springs was described as around \$15, and up to \$20, and that it was around \$10 in Adelaide.



A review of a series of consecutive reports of forged or altered prescriptions to Drugs and Poisons Regulation of the Victorian Department of Health in 2012 found that reports of prescriptions forged to obtain benzodiazepines was prevalent. When 96 consecutive reports of all forged prescriptions were examined to identify those where a benzodiazepine was sought and determine the particular benzodiazepine reported to be sought by forgery, alprazolam and the brand names Xanax® and Kalma® comprised 65.4% of all benzodiazepine reports.

Forged and altered benzodiazepine prescription reports: Victoria, 96 consecutive reports 2012.



Other crime associated with alprazolam.

Best et al report a study of the relationship of benzodiazepine use and crime among substance using offenders recruited through the criminal justice system in Melbourne³⁷. These offenders reported high rates of diazepam (84% in the month prior to the index offence) and alprazolam (75% for the prior month) use. There were multiple diversion points involved in acquiring benzodiazepines. There was widespread access to prescriptions for 'fake' as well as 'real' symptoms, as well as high levels of street purchasing – particularly for alprazolam. Additionally, there was considerable trading and sharing of benzodiazepines among substance-using networks. They concluded that alprazolam use is associated with both drug-related offending and increased utilisation of emergency medical resources in Victoria.

Margaret Harding, who presided as magistrate of Victoria's Drug Court for nearly a decade, described her experience of observing the worst outcomes of the criminal justice system because of Xanax³⁸. The court's purpose is to divert drug offenders from prison and into treatment provided they comply with certain conditions including drug treatment orders including undergoing regular drug screening. She was reported as believing that without a doubt Xanax was responsible for her revoking more drug orders than any other substance, including heroin, methamphetamines and alcohol

She describes: "Time after time I heard the same story. People who had struggled really hard to get off heroin and methadone start to get their lives back on track, see their kids again, and then one night on Xanax and it was all gone. They'd go out and commit a string of burglaries and not even remember they'd done it.

"And when they came before me - and these were people whose lives I came to know a lot about - and I asked, 'What went wrong?', they would tell me it was much easier to say no to heroin than to Xanax."

³⁷ Best D, Wilson A, Reed M, et al. (2012) Understanding the role of benzodiazepine use in crime. Melbourne: Victorian Department of Health

³⁸ Julie-Ann Davies. Daily Life. High anxiety. 25 July 2012. <http://www.dailylife.com.au/health-and-fitness/dl-wellbeing/high-anxiety-20120716-225qd.html> (accessed 17 January 2013).

Pharmacy robbery in US.

The New York Times reported in 2011 that there were 1,800 robberies of U.S. pharmacies in preceding 3 years, and the most common drugs targeted were hydrocodone, oxycodone and Xanax³⁹.

Driving.

Benzodiazepines are commonly found in blood samples taken from drivers involved in major trauma accidents in Australia⁴⁰. Ogden et al reported on benzodiazepines and the risk of collision in Victoria, Australia⁴¹. They studied 184 injured drivers and report that while diazepam accounted for 51% of detected benzodiazepines, alprazolam at 11% had the most concerning contribution to collisions with 94% of those detected culpable. The contribution of alcohol in combination with benzodiazepines was significant, particularly in excess of the therapeutic range. They recommended the rescheduling of alprazolam to Schedule 8 should be discussed given that only one of 44 alprazolam drivers had no other drugs in their system or blood levels were within the therapeutic dose range. They also reported that these results probably indicated that this group of drivers were using alprazolam outside normal prescribing patterns possibly indicative of an abuse pattern.

Responses of Australian regulatory authorities to problems with alprazolam.

As a result of evidence and reports of particular problems with alprazolam, a number of State and Territory regulatory authorities have communicated concerns to medical practitioners either through leaflets, web pages, or articles in medical registration boards. See attachments 2-5.

Tasmania. (See Appendix 2). Concern about problems with alprazolam in Tasmania emerged in the mid-2000s, because of concern as follows

- the per capita prescription rate was double that of national rate
- there were repeated reports of cases of morbidity and mortality involving alprazolam
- A Working party involving the RANZCP, RACGP, and State government representatives was formed in 2006 to develop a response.
- Education sessions to regions began in 2007
- Regulatory changes were enacted in 2007:
 - Pharmacy were required to report monthly on alprazolam dispensing
 - a permit was required when prescribing alprazolam for more than >4 weeks where opioids also prescribed
 - approval was required for patients receiving opioid substitution therapy for opioid dependence (OST)

Victoria. (See Appendix 3). Needle and Syringe Program staff in Melbourne had reported increasing antisocial behaviour, particularly opportunistic criminal activity, believed to be associated with alprazolam use, and problems with violent and aggressive behaviour within the program shop fronts, for which they had no memory the next day when they returned. This behaviour was linked to the use of alprazolam, which NSPs described as "angry pills". These findings prompted the Medical Practitioner's Board of Victoria (MPBV) to issue a warning in June 2009 to all registered practitioners in the state that 'alprazolam is more subject to non-medical use, and causes a disproportionately high level of serious harm, than other benzodiazepines', recommending that 'alprazolam should only be prescribed where there is a clear indication for its use'⁴².

Northern Territory. (See Appendix 4). The Chief Health Officer of the Northern Territory informed general practitioners and psychiatrists in the Territory that over the past year several

³⁹ Goodnough A. Pharmacies besieged by addicted thieves. New York Times, 6 February 2011.

http://www.nytimes.com/2011/02/07/us/07pharmacies.html?pagewanted=all&_r=0 (accessed 15 January 2013).

⁴⁰ Ch'ng CW et al. Drug use in motor vehicle drivers presenting to an Australian, adult major trauma centre. *Emerg Med Australas* 2007;19:359-65.

⁴¹ Ogden EJD et al. Benzodiazepines and risk of collision Presentation to the Australasian Professional Society on Alcohol and Drugs 2012 Annual Conference. 2012.

⁴² Medical Practitioners Board of Victoria. Warning: Alprazolam (Xanax, Kalma, Zambhexsal), Bulletin. June 2009, page 11.

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people had been admitted to hospital with severe ischaemic limb damage and disability associated with injecting of alprazolam. Also that increasing other problems associated with inappropriate oral use as well as injecting. In addition, the letter reported growing concern nationally about the escalating harms associated with abuse of benzodiazepine generally, in particular alprazolam, and the need to exercise great care in prescribing.

The letter described that benzodiazepines, in particular alprazolam, are often sought to enhance the 'high' of injected opioids.

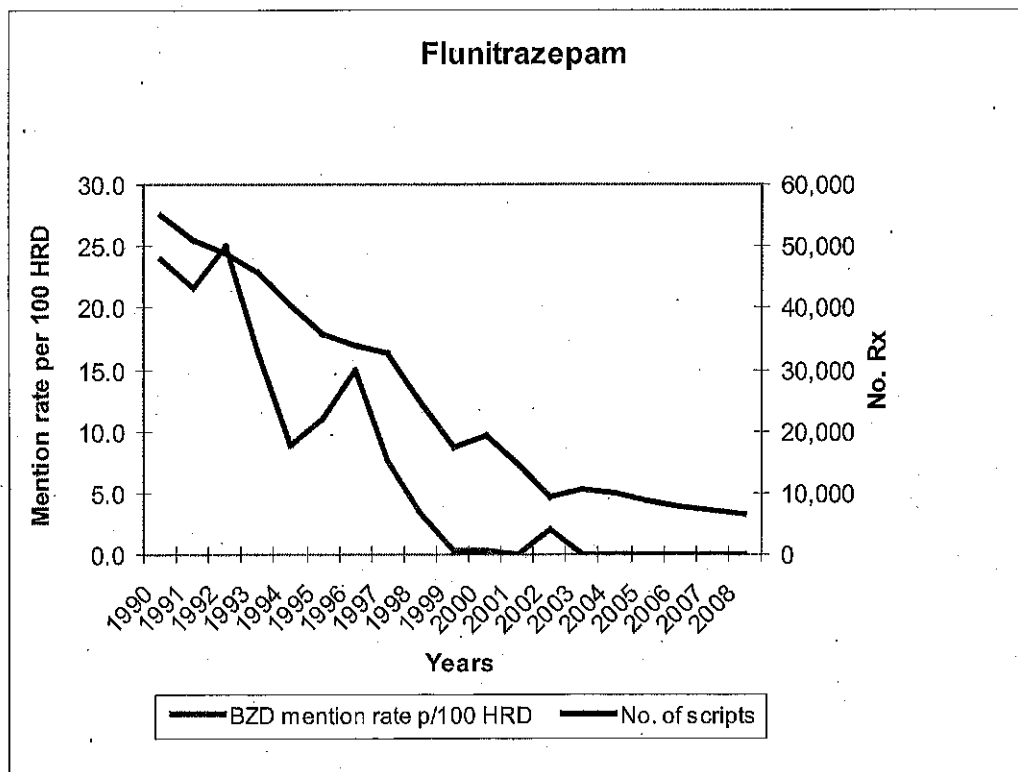
The letter also described the lucrative street price of a single 2 mg tablet of alprazolam in Darwin and Alice Springs at around \$15, and up to \$20, and that it was around \$10 in Adelaide.

South Australia. (See Appendix 5). The Drugs of Dependence Unit of South Australian Department of Health provide a resource for prescribers in that State. It described that alprazolam abuse was being more frequently reported. It warned prescribers about the risk of being identified as a 'script doctor'.

Will selective rescheduling of alprazolam to Schedule 8 merely shift the choice of benzodiazepine for misuse to another equally harmful benzodiazepine?

In recent years particular problems with individual high-risk benzodiazepines resulted in regulatory responses that resulted in considerable public health benefits, and concerns that those misusing them would merely shift to another benzodiazepine for misuse proved unfounded.

Flunitrazepam (Rohypnol). When flunitrazepam was rescheduled to Schedule 8 in 1993 because of concerns about its abuse liability, preference for it by people who inject drugs, and association with drug facilitated sexual assault, there was no shift to misuse of other benzodiazepines, but there was a favourable result in a decrease of detection of this drug in heroin-related deaths in Victoria (See figure). Roche pharmaceutical company removed their 2 mg product Rohypnol from the market, and it was replaced with a 1 mg tablet.



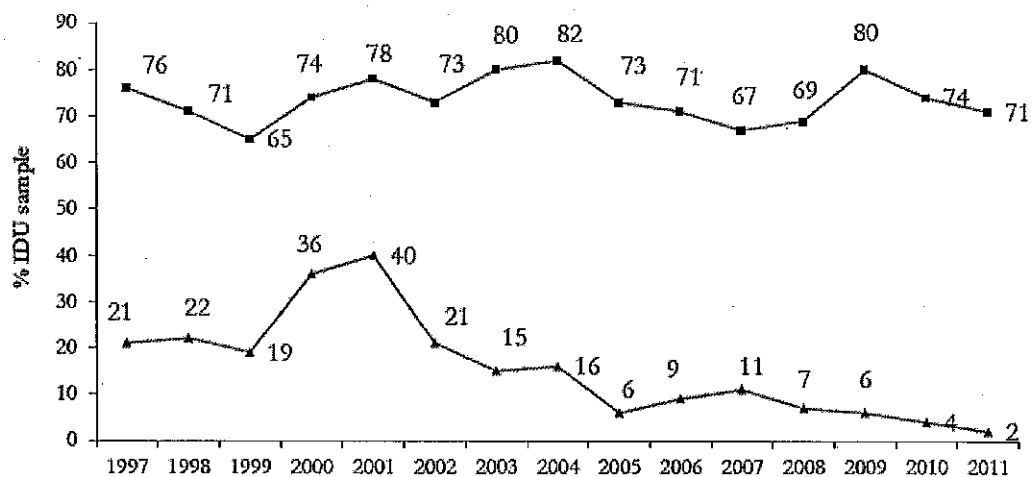
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Temazepam gelcaps. When injection of the liquid contents of temazepam gelcaps became prevalent among PWID, and was causing considerable problems with ischaemic limb injury and gangrene, and other vascular and associated problems at the time of the heroin shortage in 2000, the response was first to limit access to the capsules as a PBS subsidised drug while continuing to leave temazepam tablets available as a subsidised drug. The gelcaps were subsequently removed from the market in 2002. There was concern then that PWIDs would merely shift to misusing and injecting other benzodiazepines.

History reveals that injection of temazepam by PWIDs, and benzodiazepine injection generally, has plummeted and remained at very low levels subsequent to the PBS changes and removal of the readily injectable gelcaps from the market.

This graph (the lower curve) describes trends in injecting of benzodiazepines by IDRS subjects in Victoria⁴³.

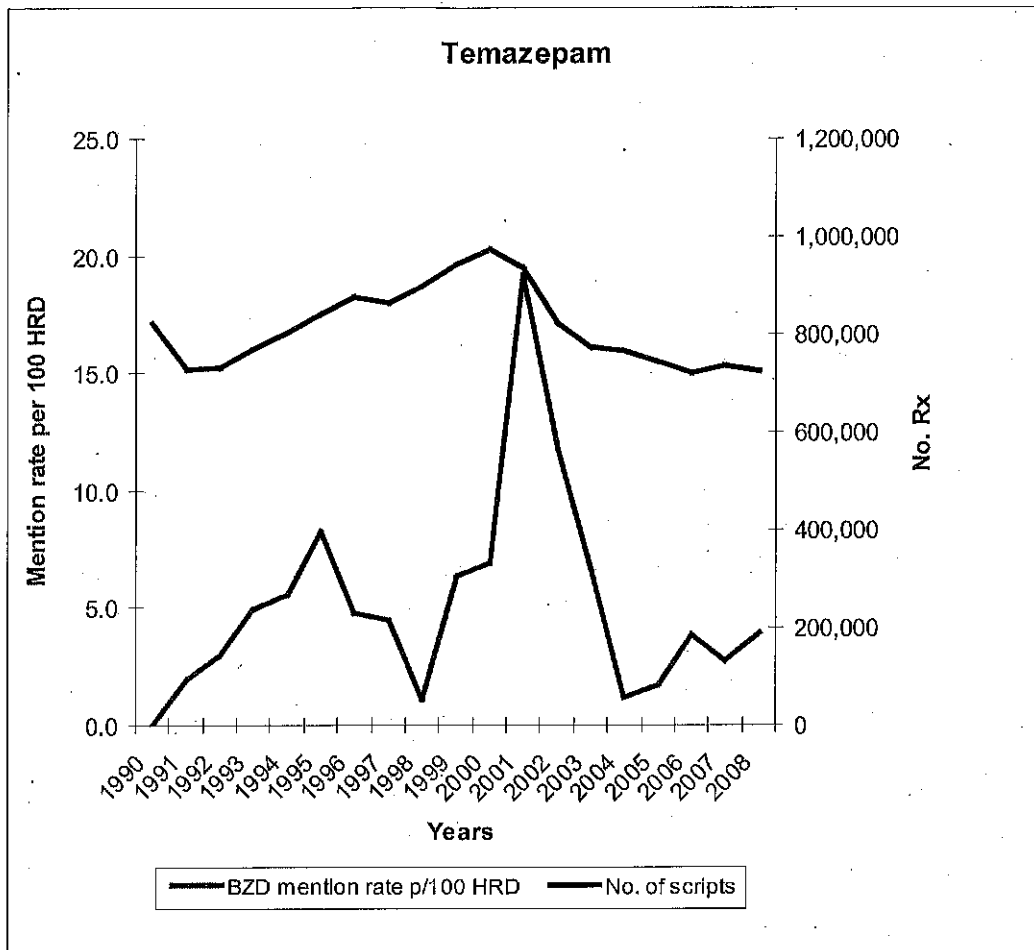
Figure 7: Percentage of PWID reporting recent benzodiazepine use and injection, 1997-2011



Detection of temazepam in heroin-related deaths in Victoria, which peaked at the height of the heroin shortage, plummeted subsequent to the removal of the gelcaps from the market.

⁴³ Kirwan A et al. Drug Trends 2011. Findings from the Illicit Drugs Reporting System. Macfarlane Burnet Institute for Medical Research and Public Health and Turning Point Alcohol and Drug Centre Australian drug Trends Series No 76, Melbourne 2012

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**APPENDIX 1: Extract from Drugs and Crime Prevention Committee of
the Parliament of Victoria Inquiry into the Misuse/Abuse of
Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria:
Final Report**



PARLIAMENT OF VICTORIA
DRUGS AND CRIME PREVENTION COMMITTEE

**INQUIRY INTO THE MISUSE/ABUSE OF
BENZODIAZEPINES AND OTHER FORMS OF
PHARMACEUTICAL DRUGS IN VICTORIA**

Final Report

Ordered to be printed

December 2007

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Government Printer for the State of Victoria

The Report found that:

Misuse and injecting of benzodiazepines and pharmaceutical opioids, especially morphine and buprenorphine, has become entrenched among some groups of PWID (persons who inject drugs) in Melbourne. The findings suggest that the drugs are diverted to the black market and can be sold for considerable profit. The drugs may be diverted from legitimate prescriptions and prescribed doses, via doctor-shopping, or from forged prescriptions or stolen drugs. Prescription drugs appear to be relatively easy to obtain on the street, and seem to be available from a diffuse network of users, friends of users, dealers and suppliers, some of who also sell all kinds of illicit drugs. The findings also suggest criminal behaviour may be related to the dependence on, and the use of, prescription drugs; for instance shoplifting, property crime, drug dealing, violence and intoxicated driving. In addition, disinhibited, aggressive, and bizarre behaviour, and feelings of invincibility, were attributed to the drugs, in particular benzodiazepines (NDLERF 2007, p.xxviii).

The NDLERF Report is a valuable addition to a hitherto paucity of material on prescription drug abuse. Nonetheless, it is still true as the Victorian Alcohol and Drug Association (VAADA) states in a submission to this Inquiry that 'there is little statistical data available examining the social and criminal impact of misuse of pharmaceutical drugs in Victoria'.⁹² The NDLERF Report also acknowledges this (NDLERF 2007, p.xi). Consequently, VAADA recommends to the Committee that:

Statistical data be gathered concerning the social and criminal harms associated with the misuse of pharmaceutical drugs; and that this data be used to inform the development of Victorian government alcohol and other drug policy.

VAADA considers that the following factors should be taken into account when gathering statistical data relating to the social and criminal harms associated with misuse of pharmaceutical drugs:

- That misuse of pharmaceutical drugs often occurs in a context of polydrug use and it would require careful analysis to distinguish the harms associated with one drug from another,
 - It may be the case that cultures/patterns of polydrug misuse (including pharmaceuticals) will be best explained by qualitative research;
- That many of the harms associated with pharmaceutical misuse impact through family and relationship breakdown. Given the difficulty of quantifying some of these harms,
 - It may be the case that these sort of harms are best understood through qualitative rather than quantitative research.⁹³

A note on alprazolam (Xanax)

Throughout this chapter benzodiazepines have been discussed in a generic sense without very much differentiation between one type of drug within the class and another. This has been because as a general rule both the positive and negative aspects of the benzodiazepines could be viewed as being generally applicable to most drugs within the class. One possible exception to this rule however, is arguably the drug alprazolam, commonly known as Xanax.

Xanax is a benzodiazepine prescribed to alleviate anxiety and related conditions. It is a drug with a particularly high potency, short onset and longer duration of action, which makes it a preferred drug for recreational abuse.⁹⁴ Whilst it is acknowledged as being a useful drug

⁹² Submission of the Victorian Alcohol and Drug Association (VAADA) to the Drugs and Crime Prevention Committee Inquiry into the Misuse/Abuse of Benzodiazepines and other Forms of Pharmaceutical Drugs in Victoria, June 2007.

⁹³ Submission of the Victorian Alcohol and Drug Association (VAADA) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

⁹⁴ See comments of Joseph Rannazzisi made in a presentation to the Drugs and Crime Prevention Committee, Washington, July 2007 (Drug Enforcement Administration (DEA) 2007a).

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in treating anxiety, concerns have been expressed by many witnesses who gave evidence to this Committee that Xanax, particularly when used for recreational purposes, or administered in the wrong way can be particularly dangerous.⁹⁵ Experts in the field have also testified to its highly addictive qualities and the difficulties associated with withdrawing from the drug – even more so than with other forms of benzodiazepines. For example at a forum on prescription drug abuse in Bendigo, Ms Penny Buykx of the Faculty of Health Sciences, La Trobe University, stated to the Committee that:

Xanax dependence is one of the most difficult to assist people with because of the half-life of the medication and the immediate drug effect. If a person is feeling quite jittery, Xanax is fantastic at fixing the symptoms immediately but it is quite difficult to deal with. It is also difficult if you are transferring someone from that medication to a longer acting medication in order to do a gradual withdrawal. It is harder to get an accurate equivalent. So I am interested in alprazolam and why it has become so popular, because it seems that some of the harms associated with it are more than amongst some of other benzodiazepines.⁹⁶

Similar concerns have been expressed about Xanax in other rural areas of the state⁹⁷ including Swan Hill⁹⁸ and Echuca.⁹⁹

Dangers associated with inappropriate Xanax use are not restricted to rural Victoria. Reports of its abuse have also surfaced from urban Melbourne. For example, Dr Mark Stoové of Turning Point Alcohol and Drug Centre, drawing from Turning Point research, told the Committee that:

Key informants are saying that Xanax is increasingly becoming popular both as a licit prescription amongst injecting drug users but also being used illicitly.¹⁰⁰

Dr Stoové's colleague Mr Peter Muhleisen, senior pharmacist at Turning Point, added:

What has happened is that whilst alprazolam has been promoted primarily for anxiety disorders, which it is appropriate for, drug-using populations have found that that is the drug that gets the effect that they like. Xanax has now become the hot new drug after they cannot get temazepam any more [due to a change in drug formulation].¹⁰¹

Of equal concern to some witnesses appearing before the Committee was that alprazolam appears to feature more prominently in crime related activity such as diversion and theft. For example in a submission to this Inquiry by the Pharmacy Board of Victoria, it was stated that it is not uncommon for Xanax tablets (100) to be prescribed and dispensed as private

95 Alprazolam is a benzodiazepine in pill form which is not soluble in water. Injecting this drug therefore can result in major medical complications similar to those that have occurred when the benzodiazepine temazepam is injected (see discussion later in this chapter).

96 Ms Penny Buykx, Research Officer, Faculty of Health Sciences, La Trobe University, Bendigo, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Prescription Drug Forum, Bendigo, 30 May 2007.

97 And also particularly in rural areas of the United States such as the Appalachian states of Kentucky and West Virginia. See discussion in Chapter 4.1 and see also Leukefeld et al 2007; Havens, Leukefeld & Walker 2006. In this regard Joseph Rannazzisi of the United States DEA has presented statistics to this Committee detailing that alprazolam was ranked third in the number of prescriptions for controlled substances in the USA from 2003 to 2006 inclusive and that it was ranked 7th for all sales of generic pharmaceuticals for those years (Drug Enforcement Administration 2007a).

98 See the Submission of Dr Mike Moynihan, President of the Rural Doctors Association (Victoria) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

99 See the Submission of Ms Dot Moon, Alcohol and Other Drugs Withdrawal Co-ordinator, Echuca Regional Health, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

100 Dr Mark Stoové, Research Fellow, Turning Point Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

101 Mr Peter Muhleisen, Senior Pharmacist, Turning Point Alcohol and Drug Centre, Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 9 July 2007.

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prescriptions and then on-sold on the street at \$5.00 per tablet.¹⁰² A submission from Youth Projects, a Melbourne based provider of drug and alcohol services for young people, has even reported anecdotal evidence of the stronger formulations of benzodiazepines, particularly Xanax, being used as a 'date rape' drug and/or to facilitate robberies.¹⁰³ Whilst such reports are disturbing there is insufficient evidence of this happening to constitute an established trend.

Given these concerns it is not surprising that in some quarters there have been calls for stronger regulation of the prescribing of Xanax. For example, a submission from a group of clinicians working in the Victorian public hospital sector noted that alprazolam (Xanax) is only listed at Schedule 4 despite the concerns of many clinicians:

The overwhelming consensus among alcohol and drug clinicians is that alprazolam is one of the most widely abused of the benzodiazepines, and that management of withdrawal of patients using alprazolam is particularly difficult.

While recognising that the scheduling of medications is currently administered at Commonwealth level, it is appropriate that the idea of rescheduling be raised in this document. Given the extent of abuse of alprazolam and the risks of withdrawal and overdose associated with this benzodiazepine, a change in schedule to S8 (alongside drugs like morphine and oxycodone) would be a positive public health measure. This change in regulation would increase the controls on alprazolam prescribing, may restrict duration of prescribing of this drug and could raise prescriber awareness of the risks of alprazolam.¹⁰⁴

This is in fact a path that one state has gone down. In 2006 a review was conducted in relation to alprazolam prescribing in Tasmania. As a result of the review it was recommended that:

- The prescribing of alprazolam will be required to be reported monthly by the dispensing pharmacist.
- This reporting will be in a similar manner as the current reporting of dispensed schedule 8 medications.
- Any prescribing of alprazolam for more than one month to persons receiving opioid analgesics will require an authority to prescribe.
- Prescribers will be notified not to prescribe alprazolam if the patient is receiving opioid analgesics from another prescriber. (Currently persons declared as drug dependent cannot have S4 drugs prescribed by prescribers other than their authorised prescriber. However this is only detected when the prescribing comes to our attention through other ad hoc reports. The branch does not have access to PBS [Pharmaceutical Benefits Scheme] data in order to detect such prescribing.)
- Patients receiving methadone or who are on the pharmacotherapy program will not be allowed to have alprazolam prescribed concurrently unless this is endorsed by the Director of Alcohol and Drug Services in accordance with the pharmacotherapy policy and guidelines.
- Consultation with the Tasmanian Branch of the Royal Australian and New Zealand College of Psychiatrists will be sought in regard to these recommendations, along with their opinion in relation to the appropriate use of alprazolam given the concerns raised in this report.

102 Submission of Pharmacy Board of Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007. See also the submission of Dr Mike Moynihan, President of the Rural Doctors Association (Victoria) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

103 See submission of Youth Projects Inc to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2007.

104 Submission of the Interhospital Liaison Group to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

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- Medicare Australia will be consulted as to possible audits of prescribing of alprazolam outside their authority criteria.
- An education campaign be undertaken through the Division of General Practice to highlight the problems with alprazolam and give advice in relation to its prescribing and use.¹⁰⁵

Many of these recommendations have now been implemented in Tasmania. In particular, the new state regulatory requirements came into effect on 1 September 2007. Prior to this date, an education campaign and information sessions were conducted under the auspices of the General Practice Divisions throughout Tasmania. Also, a clinical guideline sheet has been prepared in consultation with representatives of the Royal Australian College of Psychiatrists (RACP), the Royal Australian and New Zealand College of General Practice (RANZCGP) and the Pharmaceutical Services Branch of the Tasmanian Health Department that addresses the problem and the appropriate clinical use of alprazolam. This will be available to all medical practitioners in the state.

In their submission to this Inquiry Mr John Galloway and Ms Mary Sharpe state that increased monitoring of alprazolam will now achieve the following purposes:

- A clear picture of all prescribing, not just those prescriptions claimed on the PBS
- Ability to limit/prevent prescribing where there are concerns about safety
- Patients most at risk of misusing alprazolam will now only be able to have it prescribed under highly controlled circumstances
- Reduction in availability of alprazolam for illicit use and diversion.¹⁰⁶

It may be that rescheduling of alprazolam to Schedule 8 is an appropriate strategy.¹⁰⁷ However, there is insufficient evidence as to whether or not this is a problem in Victoria to make conclusive findings in this area. Nonetheless, it may be appropriate as a first step to conduct a review with regard to the use and prescribing of this drug.

Psychomotor Impairment and driving

Given the common side effects associated with the benzodiazepines – sedation, drowsiness, ataxia, psychomotor slowing, motor incoordination and mental confusion – it is not surprising to find that these drugs, among others, are associated with an increased risk of motor vehicle accidents, particularly when taken in larger doses or in combination with other drugs. According to VicRoads' submission to the Inquiry, 'the misuse/abuse of benzodiazepines is a major road safety issue in Victoria, with significant numbers of drivers killed and drug impaired drivers testing positive to these drugs'.¹⁰⁸

Professor Drummer, in his evidence to the Inquiry, explained that:

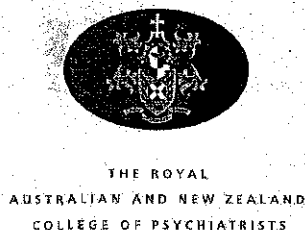
There has been a system in Victoria since 2000 for police officers to detect what was called impaired drivers. In that system, if a police officer forms the view a person is impaired and their alcohol breath-test is largely negative or very low and not consistent with their apparent behaviour, the person can be assessed at a police station by an appropriately trained assessor. If they fail that sobriety test, a blood sample can be taken by a clinical forensic physician. Our laboratory will then screen that specimen for a variety of drugs,

¹⁰⁵ Review summarised in Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services, Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

¹⁰⁶ Submission of Mr John Galloway, Chief Pharmacist and Ms Mary Sharpe, Deputy Chief Pharmacist, Pharmaceutical Services Branch, Department of Health and Human Services, Tasmania, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2007.

¹⁰⁷ For further discussion of drug scheduling, see Chapter 3.1.

¹⁰⁸ Submission from George Mavroyeni, Director, Road Safety and Network Access, Vicroads, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 13 June 2007.



THE ROYAL AUSTRALIAN
COLLEGE OF
GENERAL PRACTITIONERS

ALPRAZOLAM PRESCRIBING GUIDELINES

INTRODUCTION

Alprazolam is a short-acting drug in the benzodiazepine class of medications. It is used to treat anxiety disorders and panic attacks. It is usually taken two to four times a day. Alprazolam is sometimes used in the treatment of depression and agoraphobia. Alprazolam may cause drowsiness and affect alertness. Ideally it should only be taken for short periods of time such as 2 to 4 weeks. Benzodiazepines are very effective for treating acute symptoms, but if short acting benzodiazepines such as alprazolam are used long term, the intended effect diminishes with tolerance, there is a high risk of the development of dependency, and the rapidly fluctuating blood levels may exacerbate the symptoms of anxiety disorder.

"Benzodiazepines act more rapidly than antidepressants but are more likely to cause physical dependencies, and such adverse effects as somnolence, ataxia, and memory problems. Antidepressants and benzodiazepines are sometimes used in combination initially with a slow taper from the benzodiazepine after the antidepressant becomes effective".¹

RISKS OF COMBINING ALPRAZOLAM WITH OPIOIDS

Alprazolam, like other benzodiazepines, acts on the central nervous system (CNS). The effects of alprazolam are increased when combined with other central nervous system depressants such as methadone and other opiate related medications.

"Major clinical issues occur with the concurrent use of benzodiazepines and opiates. Benzodiazepines and opiates used together increase the risk of fatal overdose and similarly the use of methadone and benzodiazepines increases the risk of sedation."²

The mortality and harm that is associated with abuse of opioids prescribed in the community is an important emerging issue and associated with that abuse is the concurrent abuse of alprazolam (Alprax®, Kalma®, Xanax® and Zambhexal®). There are also indications that harm levels in the use of this drug are increasing in line with the steadily increasing medical use of opioids.

USE IN PANIC DISORDER

Alprazolam is approved on the Pharmaceutical Benefits Scheme (PBS) 'for the treatment of panic disorders where other treatments have failed or are inappropriate'.³

Consideration needs to be given to whether the patient is suffering from panic disorder and not a generalised anxiety disorder, or from anxiety symptoms generally, including those associated with drug abuse. Whilst isolated panic attacks are common, panic disorder is uncommon. It is quoted as affecting 2 to 3% of the population in a 12 month period and is 2 to 3 times more prevalent in women than men

¹ The Merck Manual 18th Edition, 2006, Page 1677.

² National Comorbidity Project - Comorbidity of mental disorders and substance use; National Mental Health Strategy; National Drug Strategy.

³ Schedule of Pharmaceutical Benefits August 2006 - Psycholeptics; Alprazolam

"The initial approach for the prophylaxis of panic disorder should include psychological measures such as cognitive behavioural therapy (CBT). While these will suffice for some patients, others will need drugs as well. Some patients initially do not relate to a psychological approach and cannot use CBT. They should be commenced on a first line pharmacological drug, with CBT added later if possible. Regarding effectiveness, the number needed-to-treat to get one person panic free is 3 for CBT and 5 for medication. Pharmacotherapy for panic disorder may need to be continued for 6 to 12 months in the first instance"⁴

First line therapy is stated to be "newer antidepressants particularly paroxetine and sertraline".⁵ Benzodiazepines are listed as second line therapy along with tricyclic antidepressants and MAOI's.

The bi-national Committee of Psychotropic Drugs and Other Physical Treatment (COPDOPT) take the view that there is some, be it small, evidence-based support for the use of alprazolam for short periods. In using it consideration should be given to the fact that:

- the enduring benefit is small
- cognitive and motor side-effects of long term use must be considered
- the relatively greater development of tolerance and problems with withdrawal in patients using short acting agents such as alprazolam.

In the case of drug abuse very careful consideration needs to be given to the use of benzodiazepines, with diazepam being a preferred treatment for anxiety associated with drug withdrawal. Ideally such patients should be referred to an Alcohol and Drug specialist/services.

ALPRAZOLAM ABUSE

Pharmaceutical Benefits Scheme data suggest that alprazolam prescribing in Tasmania is approximately 100% higher than the national average. Similarly the use of opioids in Tasmania is approximately 50% higher than the national average. The reported use of intravenous alprazolam in conjunction with methadone to achieve a "heroin" like high is of particular concern.⁶ In Tasmania there is an illicit drug problem associated with legally prescribed drugs and very little heroin. The practice of intravenously injecting alprazolam with methadone presents a very serious risk of overdose.

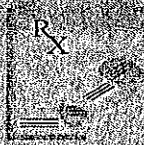
Consistent with other jurisdictional arrangements, alprazolam is listed as a declared restricted substance under the Tasmanian Poisons (Declared Restricted Substances Order 1990). This requirement means that prescriptions dispensed in Tasmania must be written by prescribers registered in Tasmania. It also places other conditions on its supply by the dispensing pharmacist as a declared restricted substance. Possession except in accordance with a legal prescription is illegal and prescribers cannot prescribe this for drug dependent persons receiving Schedule 8 medications unless they are the holder of an authority issued under S22 of the *Alcohol and Drug Dependency Act 1968* for those medications.

(Refer – DHHS – Legal requirements for the prescribing of Alprazolam) July 2007

⁴ Therapeutic Guideline: Psychotropic Version 5 Melbourne 2003; Page 176

⁵ Therapeutic Guideline: Psychotropic Version 5 Melbourne 2003; Page 176

⁶ R Bruno; Tasmanian Drug Trends 2006 – Findings from the Illicit Drug Reporting System (IDRS) NDARC.



Legal requirements for the prescribing of alprazolam

Current Regulatory Status

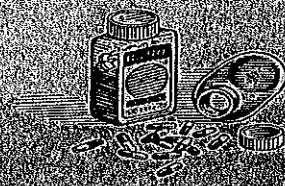
Alprazolam is listed as a declared restricted substance under the Tasmanian Poisons (Declared Restricted Substance Order 1990) commonly referred to as a S4D. This requires:

- Prescriptions dispensed in Tasmania must be written only by prescribers registered in Tasmania.
- Repeat interval must be stated on prescriptions.
- Prescription is valid for 6 months from date of writing.
- No emergency supply by a pharmacist without a prescriber's authority.
- Possession without authority is illegal unless in accordance with a legal prescription.
- Patients declared as drug dependent can only be prescribed an S4D by their authorised opioid prescriber.

Changes as of 1 September 2007

All the above requirements remain and in addition:

- All prescriptions dispensed for alprazolam will be added to the currently required monthly reporting of dispensed schedule 8 substances from Tasmanian pharmacies. (Note: alprazolam remains S4D)
- The prescribing of alprazolam for more than 4 weeks in conjunction with any opioid will require the prescriber to obtain an authority to prescribe. Authorities will be issued in a similar manner to the opioid authorities.
- Alprazolam prescribing to patients receiving a pharmacotherapy will not be legally authorised unless endorsed by the Clinical Director of the Alcohol and Drug Services. This is also a requirement of the Tasmanian Pharmacotherapy Policy.
- Prescribers will be notified not to prescribe alprazolam if a patient is already under the care of another medical practitioner who is also prescribing benzodiazepines and/or opioids.





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→ National Registration Update

→ Hearing Summaries

President's Message

From time to time the Board is required to consider suspending a medical practitioner's registration before any evidence has been tested at a hearing and sometimes before there has been a comprehensive investigation. This is one of the most onerous but important tasks for the Board in terms of balancing its primary responsibility to protect the public with the need to ensure the doctor in question is treated fairly and afforded natural justice.

In these circumstances, the Board can only consider suspending a doctor's registration if it believes, on the basis of the available information, that there is a *serious* risk to the health and safety of the public if the doctor continues to practise. The perceived risk can be based on concern about the doctor's health, their professional performance or their professional conduct.

Instead of suspending a doctor's registration the Board can, after receiving submissions in person or in writing from the doctor, decide to enter into an agreement with the doctor to alter the way he or she practises medicine. This can only happen if the Board is of the opinion that it is necessary to do so because there is a serious risk to the health and safety of the public if the doctor continues to practise without such restrictions. The Board only takes this action – which is an alternative to suspension – if it is confident that the agreement with the doctor reduces the risk of his or her ongoing practice.

The decision to suspend a doctor's registration or to enter into an agreement is not a 'finding of guilt', but is the result of an assessment of risk. After making such a decision, the onus is on the Board to investigate the matter and, when indicated, refer the matter to a hearing at the Victorian Civil and Administrative Tribunal (VCAT) as soon as possible.

The Board's power in relation to suspension is set out in detail in the *Health Professions Registration Act 2005*. These considerations are completely separate from the powers of formal hearing panels and VCAT to determine to suspend the registration of a medical practitioner after an adverse finding has been made at a hearing.

The Board takes its responsibilities very seriously and works hard to ensure that the public is protected. However, no matter is more carefully considered, or subjected to more exhaustive analysis of the available information than when the Board is considering suspending a doctor's registration. →

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President's Message (continued)

Finally, I commend to you the update on national registration published on this page of this *Bulletin*. While more detail of the national scheme will only be available when the Exposure Draft of the proposed national legislation is released, some broad principles were announced in May and warrant your consideration.



Robert Adler
President

National Registration Update

On 8 May 2009 the Australian Health Workforce Ministerial Council released a communiqué about the National Registration and Accreditation Scheme that will see the introduction of national medical regulation. The key features of this communiqué are:

- Accreditation functions will be independent of government and it is expected that the Australian Medical Council will continue to fill this role in medicine
- Applicants for registration renewal will be required to demonstrate participation in an approved continuing professional development program
- Practitioners and employers will be required to report a practitioner who is placing the public at risk through health impairment, substance abuse, a departure from professional standards or by engaging in professional sexual misconduct
- Complaints will be handled flexibly, allowing each state and territory to decide which procedures to follow. This suggests that Victoria will continue the current model in which the Board investigates notifications and decides the appropriate outcome
- The Medical Board of Australia will have nine members, at least one member from each of Queensland, New South Wales, Victoria, South Australia and Western Australia, plus one from the other states and territories. At least one member will be from a rural or regional area. At least one third, but not more than half, of the Board's members will not be medical practitioners, and two must be community members
- The national office of the Australian Health Practitioner Regulation Agency will be located in Melbourne
- The exposure draft of the *Health Practitioner Regulation National Law Bill 2009*, which will provide the legal framework for the national scheme, will be released for public consultation later in 2009.

These changes will not take effect until the new Act comes into operation in July 2010.

New Forms: Victorian Registry of Births, Deaths and Marriages

The Victorian Registry of Births, Deaths and Marriages provides information for doctors about death certification and introduced new death certification forms in December 2008. Information about reporting requirements and instructions on how to fill out the new forms can be found at <https://online.justice.vic.gov.au/bdm/home>

Warning: Alprazolam (Xanax, Kalma, Zamhexsal)

This item has been prepared by the Department of Human Services.

Recent evidence suggests that alprazolam is more subject to non-medical use, and causes a disproportionately higher level of serious harm, than other benzodiazepines.

Alprazolam is a drug with particularly high potency and short onset of action, which makes it a preferred drug for recreational abuse. As with other benzodiazepines, inappropriately high doses can cause anterograde amnesia. Anecdotal reports suggest that among the benzodiazepines, non-medical use is particularly associated with harmful experiences such as seizures, traffic accidents and crime-related harm.

Alprazolam is now the most commonly reported benzodiazepine among Australian injecting drug users who report injection of benzodiazepines.

Many witnesses giving evidence to the Victorian Drugs and Crime Prevention Committee's *Inquiry into Benzodiazepines and other Pharmaceutical Drugs in Victoria* expressed concerns that alprazolam, when used for recreational purposes, can be particularly dangerous. They commented on its highly addictive qualities. The Senior

Pharmacist at Turning Point Alcohol and Drug Centre commented that for the drug-using population, alprazolam provides the effect they want. Others commented that alprazolam appears to feature more prominently in crime-related activity such as diversion and theft.

The Pharmacy Board of Victoria stated that it was not uncommon for alprazolam (Xanax) tablets (100) to be prescribed and dispensed as private (non-PBS) prescriptions and then on-sold on the street for \$5 per tablet.

The Victorian Interhospital Liaison Group expressed concern that alprazolam is one of the most widely abused of the benzodiazepines and that management of withdrawal was particularly difficult.

Most recently, alarming reports from several Needle Syringe Programs (NSPs) describe the effects of high-dose non-medical use of alprazolam by their clients causing problems of anger and aggression, as well as violent and threatening behaviour, which the users do not remember the next day. During these episodes it is not possible to reason with or calm individuals. Alprazolam tablets are also known as 'angry pills'. Some NSPs report that people affected by high doses will commit crimes such as shoplifting but will be unaware of their surroundings.

When they recover in the police cells they do not remember the actions that led to their arrest. When intoxicated they appear to be more at risk of either committing or being the subject of violence, as well as of falls and other injury as a result of intoxication.

There has been particular concern in Tasmania about prescribing and non-medical use of alprazolam. A circular to pharmacists in that state noted that serious injury and death has resulted from the practice of injecting alprazolam alone, or with other drugs, to produce a heroin-like 'high'.

Alprazolam should only be prescribed when there is a clear indication for its use, after taking into account the risks to the patient and the burden of harm to the community.

The recommendation of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) is that alprazolam has a limited role in the treatment of panic disorder and anxiety. The initial approach should be psychological measures, such as cognitive behavioural therapy. First line drug therapy for panic disorder is stated to be the newer antidepressants, particularly paroxetine and sertraline. Benzodiazepines are listed as second line therapy along with tricyclic antidepressants and the MAOI's. This approach is supported by the PBS approval, which is 'for the treatment of panic disorders where other treatments have failed or are inappropriate'.

Training DVD: Professional Challenges

In a joint project with the Royal Australian College of General Practitioners (RACGP), the Board has developed a training DVD to provide guidance for doctors. The project, funded by the Department of Human Services, explores some of the most common and professionally challenging situations faced by medical practitioners.

The DVD features registered medical practitioners in consultation with patients (played by actors) in a range of common and challenging scenarios. The scenarios explore issues that are frequently involved in complaints to the Board, including blurred boundaries, drugs of dependence, patient confidentiality, terminating doctor-patient relationships, sexual misconduct, medical certificates and issues related to young people and consent. Each scenario is followed by an expert panel discussion that analyses the key issues and provides clear guidance.

The Board will give free copies of the DVD to medical practitioners granted specific registration, many of whom are international medical graduates seeking support and guidance as they make the transition to the Australian healthcare system. Copies will also be available for sale through the RACGP.

Doctor's Health: A Case Study

To ensure there is no potential for a breach in confidentiality, the following case study is fictitious, though there are familiar features in the history. The Board publishes it to illustrate its approach to dealing with practitioners whose health is impaired.

The Board believes that it deals with practitioners with health concerns in a balanced and sensitive way. It has no role in punishing doctors. Rather, its primary role is to protect the public and, in general, it can do this while supporting individuals to remain in practice and encouraging them to receive good medical care.

The Board has an active health assessment and monitoring program that draws on the expertise of Board members through the Health Committee and Board appointed specialists who provide independent advice.

Case study

Dr JG is a 42-year-old general practitioner with a history of migraine for which she had never sought treatment from another practitioner. After the breakdown of a significant relationship, she became increasingly depressed with more frequent episodes of migraine, all of which were having an impact on her ability to function adequately at work. She was too embarrassed and concerned about her confidentiality to consult a medical practitioner for medical care. She therefore began taking antidepressants that she sourced from drug company sample packs, although she stopped taking these after experiencing side effects.

In desperation during one particularly debilitating migraine, Dr JG self-injected pethidine from her doctor's bag supply. The migraine ended enabling her to sleep well and go to work the next day feeling refreshed. With each subsequent migraine, she would leave work when she felt that she could no longer function properly and after going home, would self-inject pethidine. Each time she told herself that she would not self-inject again, but she could not stop.

After Dr JG's doctor's bag supply was depleted, she wrote prescriptions in the name of patients and started to present them to the pharmacy collecting 'for the patient'. The pharmacist became suspicious about this new practice of picking up pethidine for patients, as he knew that the doctor had rarely obtained pethidine for her doctor's bag supplies until recently. He shared his concerns with Dr JG's employer, who confronted her after the practice had closed one evening. Dr JG denied self-administering pethidine, but after going home, tried to commit suicide. She was found after her principal could not contact her when she rang to check on her after the confrontation.

Dr JG was treated for the acute suicide attempt and the treating doctor, concerned that she was a risk to her patients, informed the Board.

After the overdose, Dr JG was referred to a psychiatrist and neurologist for treatment. On their advice, she voluntarily stopped practising. After informing the Board that she had improved, an independent assessment was arranged to inform the Board's actions.

With her consent, Dr JG's treating doctors supplied reports to the Board. The treating doctor reports and the independent report confirmed that Dr JG had been suffering from depression and migraines, neither of which had been appropriately treated. She had been abusing pethidine but was now receiving treatment and her health conditions were reasonably well controlled. There was no evidence of any ongoing drug abuse.

The Board negotiated conditions with Dr JG that included:

- thrice weekly urinary screening
- not possessing, prescribing or administering any Schedule 8 drugs
- to attend the Victorian Doctors' Health Program and enter into and abide by a Case Management, Aftercare and Monitoring Program (CAMP) Agreement
- receiving treatment from a treating doctor who would provide the Board with regular reports about her health
- finding a general practitioner who would coordinate her care
- working in a group practice approved by the Board, with the principal of the practice to be aware of the conditions on her registration and to provide the Board with regular reports
- limiting the number of clinical hours worked.

The Board monitored Dr JG closely. She complied with the conditions and reports from her employer and treating doctor were supportive. Her depression and migraines were being managed effectively. Over the subsequent five years, the conditions were gradually reduced and eventually removed. →

The Pre-vocational General Practice Placements Program

Lessons

The Board negotiates conditions when it believes that a doctor's health may affect their ability to practise. The primary aim of the conditions imposed on the doctor's registration is to reassure the Board and the public that the doctor's health is being managed and therefore, that any risk to the public is minimised. The conditions are also intended to support the practitioner. The imposition of conditions enables medical practitioners to return to work in a safe, controlled and supportive way. If a doctor's health deteriorates and there is a concern that the practitioner may pose a risk to the health and safety of the community, treating doctors are required to inform the Board.

The Board acknowledges that it can be difficult for practitioners to have conditions on their registration that limit their practice. Some of the obligations associated with the conditions, such as regular or random urinary testing for drugs, can be onerous. Some doctors are concerned that the restrictions will impede their ability to work and that the need to be supervised may limit their employment opportunities. To the contrary, the Board's experience is that other practitioners and hospitals are extremely supportive of their colleagues with health concerns.

It is preferable for medical practitioners whose health is impaired to voluntarily seek medical assistance early. All doctors are encouraged to have a general practitioner whom they trust, ideally one who is independent of their practice and can provide objective and confidential assessment and treatment. Medical practitioners should not self-prescribe or self-administer Schedule 4 and 8 medications – this is illegal in Victoria.

Medical practitioners and medical students are also reminded that they can access the Victorian Doctors' Health Program (VDHP), a confidential service for doctors and medical students with health concerns. The VDHP is independent of the Board. It aims to assist practitioners so that their health concerns do not have an impact on their practice, and therefore do not need to be reported to the Board. The VDHP can be contacted on 9495 6011 or through the website at www.vdhp.org.au. The VDHP's latest newsletter is distributed with this edition of the *Bulletin*.

The Pre-vocational General Practice Placements Program (PGPPP) is an initiative funded by the Commonwealth Department of Health and Ageing that provides junior doctors with professional, well supervised educational placements in general practice as part of their training.

In essence, the program allows doctors in training to gain valuable exposure to rural general practice in a highly supported environment. It enables them to gain insight that will help them make an informed decision about their future careers.

The program aims to:

- build junior doctor confidence, exposure and interest in working in outer metropolitan and regional areas through supervised general practice placements
- increase understanding of the integration between primary and secondary health care by junior doctors
- provide an experience that may encourage junior doctors to take up general practice as a career.

On the recommendation of the Post-graduate Medical Council of Victoria (PMCV), the Board has accredited a number of PGPPP placements for intern (PGY1) training.

Trained surveyors have visited all the practices recommended by PMCV for intern training. Generally, they are established practices with a proven track record in providing education and support to trainees. The requirements and responsibilities of supervisors are considerable and this limits the number of patients that they can personally consult. The intern may see up to two patients per hour, so their presence will have minimal impact on meeting any workforce shortages. This is intended to be an educational rather than a workforce initiative.

Wave consulting model

The 'wave consulting model' (also known as parallel consulting) is used for the intern PGPPP placements. This requires that every patient assessed by the intern is also seen and assessed jointly with the supervisor. There is also an opportunity for feedback from both the supervisor and the patient.

The wave consulting model aims to maximise learning opportunities for the intern in a highly supervised environment.

The model requires that:

- patients make an appointment to see the intern and a space also be left vacant in the supervising doctor's appointment book
- the intern sees the patient and formulates the diagnosis and management plan
- the supervising doctor then sees the intern and patient in a joint review
- there be opportunities for feedback from both patient and supervisor.

The intern makes notes in the patient's file, has a provider number that allows them to generate their own pathology and imaging requests and write their own referral. They can also generate their own prescriptions but are not permitted to initiate psychotropic drugs. They are empowered and encouraged to call the supervisor at any point during the interaction with the patient for direction, advice or support.

The success of the placement depends on the level of engagement of both the intern and their supervisor. Face-to-face interactions between the learner, the patient and the supervisor are a terrific learning opportunity for all participants.

When the joint review with the supervising doctor present has been undertaken and the intern has completed writing in the medical record, the supervising doctor also makes some notes in the patient's file confirming that they have co-assessed the patient.

The Board is grateful to participating supervisors and practices for the opportunities they are giving to interns through the PGPPP.

Professional Standards Panel Hearings

Inadequate management of diabetes

A patient attended a hospital emergency department very unwell, suffering from diabetic ketoacidosis. He reported that he had attended a general practitioner (GP) earlier that day complaining of a sore throat and fever. The GP had correctly diagnosed the patient's pharyngitis and had prescribed appropriate treatment. The GP also took appropriate action when the patient complained of polydipsia and polyuria, by measuring his blood glucose and, when the blood glucose was found to be 28.6 mmol/litre, informing the patient that he was diabetic.

The emergency physician who saw the patient in hospital notified the Board that the patient had told him that the treating GP had advised him to see his own GP when he returned to England in two days.

After speaking with the GP the day after seeing the patient, the emergency physician concluded that the GP did not appreciate the need to hospitalise a patient who was not previously known to be a diabetic and who had a blood sugar level of 28.6 mmol/litre.

The Professional Standards Panel was faced with two conflicting accounts of the events. The GP said he had told the patient to go to hospital immediately and had given him a copy of the blood sugar results. The emergency physician said that when he telephoned the GP the day after seeing the patient, the GP had admitted that he had not recommended that the patient go to hospital immediately.

The Panel reviewed the GP's clinical records and noted that they were inadequate. The Panel was also critical that the GP had failed to provide a letter of referral to another doctor.

The GP assured the Panel that he knew that the patient's condition could deteriorate without treatment, as it did. He admitted that he had not advised the patient of this and agreed that it was inappropriate and dangerous not to have done so. The doctor agreed that, with hindsight, his management had been inappropriate and potentially extremely dangerous. The Panel found that the GP had engaged in

unprofessional conduct. It cautioned him that his standard of record keeping must be improved to provide adequate information to other medical practitioners. The Panel also cautioned him that it was his responsibility to ensure that patients fully understood the nature of their condition, the complications that could ensue and the proper course of action that should be followed.

Failure to pay account

A patient had attended her surgical appointment early on a Saturday morning, when there was no receptionist on duty to process the account for the consultation. After assessing the patient, the surgeon advised that she needed an operation. He took into account her clinical condition and personal circumstances, and classified her as Category 2 on the public hospital waiting list. When the patient failed to pay her account within seven days, the surgeon reclassified her to a Category 3, potentially leading to a longer wait for the operation.

The surgeon explained to the Professional Standards Panel that the patient was advised when she booked her appointment that she was required to settle her account within seven days. After receiving the account, the patient submitted it to Medicare Australia, planning to pay the surgeon in full when the Medicare Australia rebate arrived. Despite several telephone conversations with the surgeon's practice manager about the payment, the patient was not told that she risked being reclassified as a Category 3 patient if she did not pay the account.

The surgeon admitted that he did not advise the patient that he had re-categorised her. He told the Panel that he had reclassified her because she had not paid her account and not on clinical grounds.

The Panel noted that the public expects that when deciding the appropriate category to assign to a patient awaiting an operation in the public system, a medical practitioner will consider clinical issues and the patient's particular circumstances.

Patients rely on the medical practitioner's expertise and trust that this will be exercised in the patient's best interests. The Panel noted that hospital authorities rely on doctors' professional judgment when

drawing up surgical lists and that on this occasion, the surgeon's decision was not based on his professional judgment.

The Panel found that the surgeon had engaged in unprofessional conduct. It cautioned him that patients should only be categorised on clinical grounds and in the patient's best interests.

Inappropriate delegation

After performing an operation on a patient in a private hospital, the surgeon had asked his surgical assistant to provide the patient with post-operative care over the next couple of days. The assistant failed to recognise a significant post-operative complication, which led to an unacceptable delay in the patient's treatment. The patient required emergency surgery after assessment by the surgeon. Her subsequent post-operative course was complicated and included a stay in the intensive care unit.

After the incident, a hospital representative met the surgeon and informed him that it was unacceptable to delegate post-operative care to the assistant who was not qualified to provide post-operative care and not credentialed by the hospital to do so. He informed the surgeon that this practice must cease immediately. The Professional Standards Panel was given evidence that the assistant had provided some care to patients after this meeting, but had stopped doing so after the hospital informed the surgeon a second time that this practice must cease.

The Panel found that the surgeon delegated routine post-operative care of his patients to the assistant. It found this was not acceptable, as the assistant had no formal post-graduate training in surgery and had only received training from the surgeon in a very narrow area of surgical practice. The surgeon told the Panel that he regarded the assistant to be at the level of a surgical intern at a public hospital. However, the assistant's surgical training had not been subjected to any external assessment or validation, and he had not received accreditation from the hospital to provide post-operative surgical care. The Panel noted that the surgeon had shown poor clinical judgment in delegating these responsibilities to the assistant.

The Panel found that the practitioner had engaged in unprofessional conduct and reprimanded him. It also cautioned the doctor to be aware of hospital by-laws and to delegate post-operative care only to medical practitioners who were appropriately qualified and accredited by the facility to provide this care.

Formal Hearings

Formal hearings are open to the public and medical practitioners are entitled to legal representation. The Board takes great care to ensure the accuracy of the formal hearing summaries it publishes. It is Board policy not to publish in the Bulletin or the Annual Report the names of doctors found to have engaged in unprofessional conduct not of a serious nature, or those against whom allegations have not been proven, if the doctor has requested that his or her name not be published. Further details of the Board's Formal Hearing decisions are available on the website at www.medicalboardvic.org.au

Dr David Alan Bowen

Allegations

It was alleged that Dr Bowen had engaged in unprofessional conduct in that on 2 April 2007 he was found guilty by the County Court of Victoria at Melbourne of 18 indictable offences, being seven counts of gross indecency and 11 counts of indecent assault.

Dr Bowen had pleaded guilty to the offences and was sentenced to two years and eight months imprisonment, which was reduced on appeal by the Court of Appeal to two years and four months with a non-parole period of one year and four months. As a result of his convictions, Dr Bowen was placed on the Sex Offenders Register for the remainder of his life. He was released on parole on 15 July 2008.

The facts of the matter were not in dispute. Dr Bowen was convicted of seven counts of gross indecency and 11 counts of indecent assault. These offences were committed against a person in 1961 who was 12 years old at the time (Dr Bowen was an 18-year-old medical student at that time) and against another person who was 14 years old in 1971 when the offending commenced (Dr Bowen was 27 years old at that time). The sentencing Judge and the Court of Appeal described Dr Bowen's offending as predatory, exploitative, hypocritical and directed at vulnerable young boys. The Court of Appeal noted that Dr Bowen was a doctor when the offences against a 14-year-old boy commenced from 1971. At the trial, a number of Dr Bowen's patients described him as a caring, generous family doctor they trusted.

The Panel heard evidence from a number of character witnesses.

Finding and determinations

Dr Bowen was convicted of serious sexual offences under the *Crimes Act 1958*. He was sentenced to a term of imprisonment and his name was placed on the Sexual Offenders Register, the most serious penalties that can be imposed by the criminal justice system. This is a departure in a substantial manner from the standards expected of a medical practitioner and is deserving of a more than passing censure. The Panel found that Dr Bowen had engaged in unprofessional conduct of a serious nature.

In considering determinations, the Panel heard that while the offences were very serious, they had occurred a long time ago. It heard that since then Dr Bowen had led a blameless life. Dr Bowen's character witnesses all attested to the fact that he was an able, caring doctor, who had been respected by his patients.

The Panel had to balance these contrasting facts – the very serious sexual offences directed at vulnerable young boys, against the fact that the offences occurred many years ago and that, since then, Dr Bowen had led a blameless life and had been an able and caring doctor.

In this case many years had passed, however the Panel had some reservations about a change in Dr Bowen's character, simply because no evidence had been put before it indicating such a change.

The Panel cancelled Dr Bowen's registration as a medical practitioner and disqualified him from applying for registration for 12 months.

Mr Ian McColl Fitzgerald

Allegations

It was alleged that Mr Fitzgerald, formerly a psychiatrist, had engaged in unprofessional conduct when he had been re-registered as a medical practitioner, in that he transgressed professional boundaries by engaging in inappropriate sexual conduct with a former patient.

Following a formal hearing, Mr Fitzgerald's registration was cancelled from 18 December 2001. Mr Fitzgerald applied for registration on 8 May 2003 and was registered as a medical practitioner on 18 March 2004. He was subject to a further formal hearing in November 2006 and his registration as a medical practitioner was cancelled for five years from 28 November 2006.

The subsequent notifier had been a patient of Mr Fitzgerald for many years and he had treated her for a range of conditions that included eating disorders, depression and alcohol abuse. The former patient gave evidence that she and Mr Fitzgerald started a friendship in 2002 while Mr Fitzgerald was not registered. This progressed to a sexual relationship in 2003, after Mr Fitzgerald had applied for registration. The former patient gave sworn evidence and provided copies of photographs that she had taken of Mr Fitzgerald along with emails that confirmed when the photographs had been taken.

Mr Fitzgerald did not attend the formal hearing and provided a letter in response to the notification by the former patient. In that letter, he denied that he had a personal relationship with his former patient and said that he did not have a sexual relationship with her.

Finding and determinations

The Panel found that Mr Fitzgerald entered into a sexual relationship with his former patient and, on at least two occasions, engaged in sexually intimate activities with her. The Panel also accepted that while registered as a medical practitioner, Mr Fitzgerald socialised with his former patient, exchanged numerous text and telephone messages, and that they photographed each other. There was undisputed evidence that Mr Fitzgerald had treated the patient on and off for about 15 years and that she had suffered from serious mental illness, which resulted in numerous hospital admissions. Mr Fitzgerald would have clearly understood her vulnerability when he entered into a friendship and then a sexual relationship with her.

Mr Fitzgerald has been subject to two previous formal hearings that had both led to the cancellation of his registration. The allegations that were proved at both hearings were about sexual boundary transgressions with a former patient.

The Panel noted that Mr Fitzgerald was before a formal hearing facing a similar allegation for the third time. Within months of the therapeutic relationship ending, a friendship began that progressed to a sexual relationship. For Mr Fitzgerald, this was the third time he had commenced a sexual relationship with a patient or former patient. →

Formal Hearings (continued)

The Panel found that Mr Fitzgerald had engaged in unprofessional conduct of a serious nature and that the conduct constituted professional misconduct. The Panel determined that he be reprimanded for his reprehensible conduct and he was disqualified from applying for registration for five years from 6 March 2009.

Dr Vasily Borisovich Lebedev

Allegations

It was alleged that Dr Lebedev had engaged in unprofessional conduct in his dealings with one patient in that he had:

- failed to notify the Drugs and Poisons Unit of the Department of Human Services that he had reason to believe that his patient was a drug-dependent person from at least mid-2000
- from mid-2000, supplied his patient who was drug dependent with a drug of dependence, pethidine, without holding a permit to do so
- from early 2001, supplied pethidine excessively and/or unnecessarily and/or without proper regard to his patient's well being
- from early 2001, failed to properly manage his patient in that he did not take sufficient or adequate steps to treat or reduce his drug dependency.

It was also alleged that Dr Lebedev accepted payments from the patient's employer for a total amount of \$30,700 over five months for services, without providing those services.

The Panel heard that the patient had been a patient of Dr Lebedev's clinic for many years. He started attending the clinic more regularly from 1998. Medicare documentation confirmed 75 consultations with Dr Lebedev from 16 October 2000 until 18 June 2002. The patient suffered from renal colic, migraines and a lower back injury, and was prescribed Imigran, Zomig, Stemetil and Panadeine Forte. When the medication was insufficient to control the pain, doctors at the clinic, including Dr Lebedev, injected him with pethidine.

Dr Lebedev said that he had extensive experience with drug-addicted persons. The patient did not look like a drug addict, was well dressed and had no physical signs of being an addict.

The patient gave evidence that he attended Dr Lebedev's clinic two to three times per week from 1999 and that he received 100mg pethidine at each visit. He said that he did not tell Dr Lebedev he had a headache or similar condition and that he would receive an injection of pethidine without question. The patient also gave evidence that Dr Lebedev had requested payment to continue to supply the pethidine. This was done using cheques from the patient's employer. The patient said that Dr Lebedev proposed that they cover up the payments by stating that the payments were for Occupational Health and Safety services. The patient confirmed that Dr Lebedev did not provide any Occupational Health and Safety advice.

The Panel heard evidence from an independent general practitioner whose opinion was that there was no clinical justification for ongoing frequent injections of pethidine at this level, apart from perhaps for the relief of cancer pain. He said that the practice of repeated injections over four years, based on the same diagnoses with no attempt to resolve the medical issues, would not be an acceptable standard to his peers.

Findings and determinations

Dr Lebedev admitted that he failed to notify the Drugs and Poisons Unit (DPU) that the patient was drug dependent. The Panel believed that notification to the DPU should have been made by mid-1998. However, Dr Lebedev submitted that around mid-2000, his colleague had unsuccessfully applied for a permit. In these circumstances, the Panel considered Dr Lebedev's submission that he believed the application for a permit constituted sufficient notification may have some merit. Therefore, the allegation that he failed to notify the DPU that he had reason to believe that his patient was a drug-dependent person from at least mid-2000 was not made out.

Dr Lebedev admitted that he supplied his patient who was drug dependent with a drug of dependence without holding a permit to do so. However, he stated that the pethidine was supplied from the doctor's bag. In the Panel's opinion, the fact that the pethidine was supplied from the doctor's bag was no defence to this allegation.

On the basis of the expert opinion, the Panel found that Dr Lebedev supplied pethidine to his patient excessively and/or unnecessarily and without proper regard to his well being. The Panel rejected

Dr Lebedev's justification that the patient's well being was appropriately considered because the provision of pethidine enabled him to continue to work.

The Panel found that Dr Lebedev failed to properly manage his patient, in that he did not take sufficient or adequate steps to treat or reduce his drug dependency from early 2001. While the Panel noted Dr Lebedev's response that he referred the patient to a number of specialists, there were no reports received from any of the specialists, nor did Dr Lebedev know whether the patient had attended any appointments. The Panel also noted that Dr Lebedev continued to administer pethidine, and to a lesser extent morphine, for more than two years after the last of the referrals. In addition, the medical records contained no management plan or advice in relation to a drug withdrawal program.

The Panel found that Dr Lebedev accepted payment for services to the patient's employer without providing such services. The evidence revealed that the actual figure was approximately \$27,500. Dr Lebedev was unable to justify the fees to the satisfaction of the Panel.

The Panel found that Dr Lebedev had engaged in unprofessional conduct of a serious nature, being professional misconduct. The Panel determined to caution Dr Lebedev to be aware of the professional boundaries that must operate between a doctor and his patients. He was reprimanded for his inappropriate management and his disregard for his patient's well being and was required to undertake education in drug dependence. Dr Lebedev's registration was suspended for three months from 1 January 2009.

Dr Jayantilal Sadhai

Allegations

The patient had been involved in a motor vehicle accident and was taken to Dr Sadhai's clinic by ambulance, on her request. Dr Sadhai saw the patient twice on the day of the accident and also saw her three days later, when she presented with neck and back pain. It was at this consultation that the patient alleged that Dr Sadhai had touched or handled her left breast in an inappropriate manner. The patient said that Dr Sadhai came around to the front of his desk, leant forward, lifted her clothing, put his hand under her bra and held her left breast. When the patient asked him what he was doing, he stopped and said he was looking for lumps. →

The allegations at the hearing were that Dr Sadhai had engaged in inappropriate or unwelcome conduct of a sexual or harassing nature at the consultation three days after the accident. It was also alleged that Dr Sadhai failed to exercise the care and skill of a competent general practitioner during the consultation, as he had lifted the patient's bra and held her left breast when there was no clinical indication for the examination. He had also failed to adequately explain the need for the examination and to seek the patient's consent.

A further allegation was that Dr Sadhai falsified his clinical notes after receiving information from the Board about the notification. Dr Sadhai admitted that there was no proper basis for the alteration to his clinical record, in which he had added a diagnosis of mastitis.

Findings and determinations

Dr Sadhai said he had no recollection of the consultation. He did not deny that he could have lifted the patient's bra and held her breast as part of an examination during the consultation. He said that he would have done so for appropriate clinical reasons and that his normal practice would have been to explain what he was doing and to ask permission.

The Panel accepted the patient's evidence that she had made no complaint of chest pain. The Panel also accepted the evidence of a general surgeon and forensic pathologist who gave evidence on behalf of Dr Sadhai confirming that a chest and breast examination may be appropriate after a head-on collision in which the patient was wearing a seat belt, even in the absence of complaints of pain. Therefore, the Panel was unable to find that there was no clinical indication for the examination.

The patient impressed the Panel as genuine and as having a very clear and upsetting recollection of her shock at the examination by Dr Sadhai. The Panel found that if Dr Sadhai had explained what he was about to do and the clinical reason for the examination, and if he had asked permission before commencing the breast examination, the patient's reaction would not have been one of shock. There was also evidence given at the hearing confirming that within a short time of the examination, the patient had told a number of people about her shock and distress at what had happened at the consultation.

The Panel found that Dr Sadhai had not explained the need for the examination and had not obtained the patient's consent to perform the examination. By groping under a patient's clothing without explanation or consent and without inviting her to undo her bra or take off her clothing, his conduct was unprofessional and showed an inability to grasp fundamental concepts relating to intimate examination.

There was insufficient evidence to support a finding that Dr Sadhai had any inappropriate or sexual intention in performing the examination. The Panel noted that the patient's perception may have been caused by her surprise at the examination.

Dr Sadhai did not deny that he had falsified his medical record to provide an apparent reason for a breast examination. He described it as an error of judgment and said that the entry was made in panic. The Panel considered that to seek to mislead the Board and avoid a proper investigation of a notification by distorting a medical record falls short to a substantial degree of the standards of a medical practitioner of good repute and competency. It was dishonest and quite unprofessional. The Panel found that Dr Sadhai had engaged in unprofessional conduct of a serious nature.

The Panel also noted that in respect of the allegations that were proven, there were questions about the adequacy of Dr Sadhai's professional performance. If Dr Sadhai had kept adequate clinical notes of his consultations, and had not mislaid those notes, he would have known what examination he had performed, the reasons for it and he would have been able to respond to the Board on the basis of his notes. If Dr Sadhai had taken the time to conduct an adequate breast examination in a professional manner, he would have explained the need for the examination and thus would not have shocked the patient as he did.

The Panel found that Dr Sadhai had engaged in unprofessional conduct of a serious nature in failing to explain the need for the breast examination and to seek consent for the examination, and in falsifying the medical record. The Panel found that falsifying the medical record constituted professional misconduct.

The Panel determined to caution and reprimand Dr Sadhai. The Panel also determined that he undertake further education relating to communication and clinical skills.

Dr Mark Jerry Schulberg

Allegations

This formal hearing arose after an intellectually disabled woman, who was unable to consent to medical procedures, became pregnant after being raped by her father. When she was 24–25 weeks pregnant, she was presented to the day surgery facility at which Dr Schulberg practises for a termination of pregnancy. Dr Schulberg initiated the termination without obtaining the necessary consent from the Victorian Civil and Administrative Tribunal (VCAT) to perform the procedure.

The patient's father has been convicted of rape and the Panel understands that the sentence imposed is the subject of appeal.

It should be noted that Dr Schulberg was not the only professional involved in these events. In the week before the patient was brought to his clinic on 29 March 2005, her father and stepmother had taken her to two public hospitals seeking a termination. The patient's father and stepmother were informed by a social worker at one of the hospitals that the consent of VCAT was required for a termination of the woman's pregnancy. On the advice of the Office of the Public Advocate (OPA), that social worker lodged an application with VCAT for a hearing under the *Guardianship and Administrative Act 1986 (Guardianship Act)* in relation to the proposed termination. The OPA notified the police.

The intervening Easter break meant that the necessary authority for a 'special procedure' had not been obtained from VCAT before Dr Schulberg commenced the procedure.

The hearing was not concerned with whether it was legally or morally appropriate for a termination to be performed on the patient. The allegations were limited to very specific aspects of the events surrounding this particular termination. Those allegations related to the woman's intellectual disability and how that factor impacted on Dr Schulberg's management of his patient. In particular, it was alleged that Dr Schulberg:

- a. initiated a termination of the pregnancy without obtaining the consent of the VCAT as required under section 39 of the *Guardianship Act*, in circumstances when he knew, or ought to have known, of the requirement to obtain VCAT's consent for a special procedure when the patient is over 18 and is incapable of giving consent →

Formal Hearings (continued)

- b. certified that the patient:
 - i. wished to terminate her pregnancy
 - ii. attended of her own free will
 - iii. was not under duress or coercion
 - iv. understood the nature of the termination of pregnancy in circumstances when he knew or ought to have known that the patient was unable to consent to the above
- c. failed to turn his mind to the fact that the pregnancy was the result of a sexual assault.

There was a great deal of evidence heard at the six-day hearing from health professionals and social workers involved in the management of the patient, medical experts, and from the OPA.

Findings and determinations**Allegation a**

The Panel was satisfied that as a practitioner who specialises in performing terminations of pregnancy, Dr Schulberg ought to have been aware of the legal requirement contained in section 39 of the *Guardianship Act*. The Panel also considered that the level of knowledge expected of medical practitioners such as Dr Schulberg, who specialise in termination of pregnancy, should be greater than would be expected of other medical practitioners without such a specialist interest. Allegation a was therefore made out.

In considering whether this amounted to unprofessional conduct, the Panel took into account:

- expert advice that Dr Schulberg's peers would expect him to know the law
- Dr Schulberg's admission that he ought to have known of the requirement for VCAT consent in such a case
- Dr Schulberg's evidence that he had never been asked to perform a termination on a woman with an intellectual disability, but did not seek expert advice as to any legal or other impediments before proceeding
- the contemporaneous notes of the patient's general practitioner and a social worker recording of telephone conversations with Dr Schulberg's rooms, in which information was provided about the fact that an application for guardianship had been made to VCAT

- the evidence of Dr Schulberg and a member of nursing staff at the Day Surgery Unit that they each had significant concerns about the appropriate person to provide consent for the procedure.

In relation to Allegation a, the Panel found that Dr Schulberg's conduct had been unprofessional and was of a serious nature.

Allegation b

On the basis of the evidence provided, this allegation was not made out.

Allegation c

The Panel considered whether Dr Schulberg failed to turn his mind to the fact that the pregnancy was the result of a sexual assault. In particular, that he failed to make adequate enquiries as to whether the police had been notified of the sexual assault and/or proceeded to terminate the pregnancy in circumstances in which the police may not have obtained the foetal blood for analysis.

The Panel noted that the matter had been reported to the Police before the termination was initiated. In the particular circumstances, the Panel was unable to conclude that Dr Schulberg's failure to contact Police or direct his staff to do so before the commencement of the termination was unprofessional.

Determinations

The Panel reprimanded Dr Schulberg in relation to his conduct, in that he initiated a termination of the pregnancy of his patient without obtaining the consent of the VCAT as required under section 39 of the *Guardianship Act*, in circumstances when he ought to have known of the requirement to obtain VCAT's consent for a special procedure when the patient is over 18 and is incapable of giving consent.

Dr Schulberg was also required to undergo counselling that covers the law regarding informed consent for termination of pregnancy, the changes introduced to the Victorian law by the *Abortion Law Reform Act 2008* (Vic) and related matters.

VCAT Hearings

Under the Health Professions Registration Act 2005, formal hearings have been replaced by hearings at the Victorian Civil and Administrative Tribunal (VCAT), for matters that involve particularly serious allegations and when the notifications were made after 1 July 2007. The Board's policy in relation to identifying in Board publications medical practitioners involved in formal hearings applies to summaries of VCAT hearings. The Board publishes links to VCAT decisions on its website at www.medicalboardvic.org.au

Dr Soo Hua Naik

The Board referred Dr Naik's professional conduct to the Victorian Civil and Administrative Tribunal (the Tribunal) for a hearing. Initially 20 allegations were made in relation to Dr Naik's professional conduct. A further allegation was later added.

- 17 allegations related to the prescribing of benzodiazepines without proper cause
- One allegation related to Dr Naik's failure to comply with an instruction from the Drugs and Poisons Unit (DPU) of the Department of Human Services (DHS) that he not prescribe benzodiazepines to named patients without first consulting with the patients' permit holders
- One allegation related to Dr Naik placing his personal interests ahead of those of his patients by directing them not to attend a pharmacy that had questioned his prescribing
- One allegation related to breaching an agreement entered into with the Board by continuing to prescribe benzodiazepines to three patients
- The allegation that was later added concerned a finding of guilt at the Heidelberg Magistrates' Court of two charges of perjury. This was the result of Dr Naik making a false declaration to the Board that he had complied with the agreement he made with the Board.

The hearing before the Tribunal proceeded on the basis that there was an agreed statement of facts and that agreed findings would be made by the Tribunal. →

The Tribunal relied on witness statements from a representative from the DPU, an expert report from a general practitioner, statements from pharmacists and a statement from one of Dr Naik's patients whose records were involved. The evidence was not contested, although Counsel for Dr Naik explained that Dr Naik had agreed to the statement of facts and the findings for practical reasons. Initially, the Tribunal was advised that Dr Naik would not give evidence, however he later decided to do so. He was cross-examined by Senior Counsel for the Board. The Tribunal noted that, even allowing that Dr Naik may have been nervous and had only decided at the last minute to give evidence, he did not impress as a witness. The Tribunal expressed concerns about his cognitive and communication skills.

The Tribunal noted that Dr Naik had received correspondence from the DPU on 21 occasions between February 1998 and August 2006 in relation to his prescribing and notifying him of his obligations under the *Drugs, Poisons and Controlled Substances Act 1981* and the *Drugs, Poisons and Controlled Substances Regulations*.

In 2007, a DPU investigation of Dr Naik's prescribing revealed that he had been prescribing benzodiazepines to patients for whom other doctors held current pharmacotherapy permits. He was formally advised by the DPU to not prescribe drugs of dependence or Unisom Sleepgel capsules for 89 patients for whom permits to prescribe Schedule 8 drugs were held by other medical practitioners, without first consulting the permit holder. After receiving the advice, Dr Naik breached his obligations and prescribed benzodiazepines to 13 patients without first consulting the relevant permit holder. A number of those patients were among the 89 patients the DPU had drawn to the attention of Dr Naik.

The Board was notified about the breaches and Dr Naik was invited to make submissions as to why he should not be suspended from practice pending completion of the investigation and/or hearing into his professional conduct. After considering submissions made by Dr Naik, the Board entered into an agreement with him to alter the way in which he practised medicine. The terms of the agreement included that he would not prescribe Schedule 8 drugs, benzodiazepines, Unisom Sleepgels or Tramadol, and that he would provide regular statutory declarations to the Board declaring that he had complied with the terms of the agreement.

Five months after entering into the agreement with Dr Naik, the Board received information that he had issued three prescriptions contrary to the agreement. At that time Dr Naik had provided two statutory declarations to the Board, falsely attesting to his compliance with the agreement. Victoria Police were notified and Dr Naik pleaded guilty to two charges of perjury. He was fined \$5000 without conviction.

After receiving the information that he had been prescribing in breach of his agreement with the Board, Dr Naik was again invited to make submissions as to why his registration should not be suspended. After considering his submissions the Board suspended Dr Naik's registration pending completion of the investigation and/or hearing into his professional conduct.

Findings

The Tribunal found that in respect of all the allegations, Dr Naik had engaged in unprofessional conduct and/or professional misconduct.

The Tribunal said that the common features of the 17 records examined by the expert were the excessive prescribing of drugs of dependence in the absence of any demonstrated or recorded therapeutic need to prescribe such drugs and an absence of any planning for longer term management. The Tribunal accepted the expert evidence that Dr Naik should have known or suspected that the patients were drug dependent. The Tribunal commented that Dr Naik's prescribing deliberately frustrated the purpose of the constraints on Schedule 8 prescribing. Those constraints were implemented to minimise problems associated with use and abuse of drugs of dependence and in an effort to protect patients. The Tribunal also stated that Dr Naik was treating particularly vulnerable people with benzodiazepines and failed to carefully manage them.

The Tribunal had evidence in the form of a witness statement from a patient that Dr Naik had directed him to not attend a particular pharmacy that had questioned his prescribing. Dr Naik agreed he did this. The Tribunal said that to direct patients in this way suggested that Dr Naik was prescribing to support a patient's drug dependence. It also indicated knowledge of the impropriety of his prescribing and his desire to hide that impropriety.

The Tribunal stated that Dr Naik's breach of his agreement with the Board indicated a preparedness to continue to misbehave despite the promise he had made that allowed him to continue to practise.

In relation to the perjury conviction, the Tribunal said that falsely declaring to the Board compliance with an undertaking and lying on his oath demonstrated a disregard for the authority of the DPU and the Board.

Determinations

The Tribunal cancelled Dr Naik's medical registration and disqualified him from applying for registration for five years.

In reaching this determination, the Tribunal took into account previous formal and informal hearings held into Dr Naik's professional conduct. Despite previous adverse findings and determinations that were aimed at remediation, the Tribunal determined that Dr Naik had not resolved his shortcomings. The Tribunal was satisfied that Dr Naik had no insight into how poor his standard of practice has been. The Tribunal was not confident that there would not be a repetition given the number of earlier reprimands that had little effect, his disregard for specific warnings, his continued prescribing in breach of the agreement with the Board and the provision of false statutory declarations to the Board.

Dr John Swieca

Allegations

It was alleged that Dr Swieca had physically abused his patient by pushing him against the consultation room wall, grabbing his arm, dragging him across the floor and pushing him towards the consultation room door. It was also alleged that Dr Swieca had threatened the patient by saying words to the effect of 'do you want me to hurry you up again?'. →

Dr Swieca denied the allegations and the hearing before the Tribunal focused on examining two strongly disputed versions of what actually happened in Dr Swieca's consulting rooms on 27 August 2007. →

VCAT Hearings (continued)

Dr Swieca is a respiratory physician specialising in sleep disorders. The patient was referred to Dr Swieca for an opinion and management in relation to snoring. He saw Dr Swieca in the consulting rooms a total of four times. At the first consultation, Dr Swieca was 1¼ hours late for the appointment. The patient had telephoned Dr Swieca's rooms before the second consultation and had been informed that Dr Swieca was running one hour behind, so the patient attended an hour later than his scheduled appointment. He had to wait a further 45 minutes. The patient rang Dr Swieca's rooms before the third appointment and he was told that Dr Swieca was running one hour late, so he again attended an hour later than his scheduled appointment. He had to wait a further 45 minutes before seeing Dr Swieca.

On the day of the events that are the subject of this hearing, the patient had asked for the first appointment of the day at 9.30am, in the hope that Dr Swieca would be more punctual. The patient was seen at approximately 10.05am.

The patient told the Tribunal that at this fourth consultation, he complained to Dr Swieca about being late and made it clear that he was unimpressed. The patient said that Dr Swieca told him to 'get out' and that there was then a verbal exchange between them. Dr Swieca then moved around his desk, reached out and pushed the patient, causing him to hit the consulting room wall. After the patient fell to his hands and knees, Dr Swieca grabbed him by his arm and tried to drag him towards the door. When the patient was able to stand, Dr Swieca pushed him towards the door. The patient said words to the effect of 'what am I supposed to do now?' and Dr Swieca said words to the effect of 'I don't care, do you want me to hurry you up again?'.

The patient gave evidence that after leaving Dr Swieca's office he immediately rang his general practitioner and his partner in an upset state and informed them of what had just occurred. Both the general practitioner and the partner confirmed their telephone conversation with the patient.

Dr Swieca denied the incident occurred in the manner alleged by the patient. He said that the patient had abused him for being late, despite Dr Swieca apologising for this. He asked the patient to leave, noting that this was the first time he had asked a patient to leave his rooms in more than 20 years of practice. When the patient refused to leave, Dr Swieca said that he tried to lead him out of the room with light contact and that the patient probably caught his foot on the leg of the chair and fell.

The Tribunal said the case came down to who it believed and why. The Tribunal was persuaded to accept the patient's version of events on the balance of probabilities and with a high level of satisfaction and confidence, based on the evidence. The Tribunal stated that it preferred the evidence of the patient, who presented as a reliable and honest witness, including his response to a lengthy cross-examination. There was no reason for him to make up the story and he reported the incident immediately to other people and to the Board later that same day.

Dr Swieca presented as a less reliable witness and aspects of his evidence were found to be implausible or unlikely. The Tribunal also found to be unreliable much of the evidence of a witness for Dr Swieca who had entered the room during the incident.

Findings

The Tribunal found that Dr Swieca had engaged in professional misconduct and commented that the physical abuse of a patient clearly falls well short of what might be expected of a medical practitioner by his professional peers. Such physical abuse of a patient cannot be tolerated under any circumstances. Even if Dr Swieca's conduct was a one-off isolated outburst that started off without undue malice but got out of hand, it was inexcusable. The verbal threat by Dr Swieca following the physical abuse also amounted to professional misconduct.

Determinations

In reaching a determination, the Tribunal took into account Dr Swieca's unacceptable behaviour and his subsequent attempt to re-cast the facts in an endeavour to rationalise his behaviour and deflect blame. In most instances, this would warrant a period of suspension, however, the Tribunal recognised that there were mitigating circumstances. The Tribunal stated that Dr Swieca had an unblemished record as a medical practitioner insofar as it was aware. This incident appeared to be an isolated outburst, perhaps triggered by a phone call communicating distressing news and exacerbated by the patient's unwelcome (but justified) complaint about his timeliness for appointments.

The Tribunal determined to reprimand Dr Swieca. It also determined that Dr Swieca must conduct his practice so as to take all reasonable measures to ensure that his patients not be kept waiting for undue periods of time for their appointments with him. Dr Swieca was ordered to undergo counselling in anger management.



TO ALL NT GENERAL PRACTITIONERS & PSYCHIATRISTS

Dear Doctor,

Re: ALPRAZOLAM AND BENZODIAZEPINE PRESCRIBING

I am writing to you to address a situation of mounting concern in the Northern Territory.

Over the past year, we have seen several people admitted to hospital with severe ischaemic limb damage and disability associated with injecting alprazolam. We are also seeing an increase in other problems associated with inappropriate oral use as well as injecting.

As well, there is growing concern nationally about the escalating harms associated with abuse of benzodiazepines generally, in particular alprazolam, and the need to exercise great care in prescribing.

This is documented in the August edition of the Australian Journal of Family Practice (AFP) by Monheit **"Currently, alprazolam and oxycodone are the most abused drugs in Australia"**

<http://www.racgp.org.au/afp/201008/201008monheit.pdf>

In June 2009, the Bulletin of the Medical Practitioners Board of Victoria warned doctors that **"Recent evidence suggests that alprazolam is more subject to non-medical use and causes a disproportionately higher level of serious harm, than other benzodiazepines"**. It documents the associated anger and aggression, violent and threatening behaviours, death and serious injury for the user, as well as criminal activity.

I have attached a copy of this Warning, plus a 2007 Tasmanian Health Department advisory ALPRAZOLAM PRESCRIBING GUIDELINES endorsed by RACGP and RANZCP.

http://www.dhhs.tas.gov.au/data/assets/pdf_file/0020/46514/Alprazolam_prescribing_guidelines.pdf

These Guidelines do NOT support prescribing alprazolam for patients with anxiety other than panic disorder, which is to be distinguished from panic attacks, panic disorder being uncommon.

Alprazolam is NOT considered a first line treatment when patients do suffer from panic disorder. First line pharmacological drugs are newer antidepressants particularly paroxetine and sertraline. An initial approach to panic disorder prophylaxis should include Cognitive Behaviour Therapy (CBT). Some patients who initially cannot use CBT should be commenced on first line pharmacological drugs.

Further, they warn about the particular hazards when there is concurrent use of opiates, including the risk of fatal overdose, and advise that patients with drug abuse should be referred to an Alcohol & Drug specialist/service.

Like the incidents documented in the Victorian document, patients in the NT have presented with acute memory blanks, confused and unable to recall the events of 1 or 2 days, the quantity of alprazolam they have used, their concomitant drug use, and unable to believe that they have "lost a couple of days of my life".

Benzodiazepines

We have also seen individuals demonstrating disinhibited behaviour and aggression with intoxication, as well as agitation and aggressive behaviours when blood levels fall.

We have increasingly seen problems related to the well documented effects that occur with benzodiazepine abuse generally, such as dependency and dose escalation, somnolence, ataxia, long term and acute memory problems. The rapidly fluctuating blood levels associated with alprazolam can particularly exacerbate anxiety symptoms.

Benzodiazepines, particularly alprazolam, are often sought to enhance the 'high' of injected opiates. Also to ameliorate the 'come down' from stimulant/amphetamine use, or symptoms of opiate withdrawal.

Note the lucrative street price of a single 2mg tablet of alprazolam in Darwin and Alice Springs at around \$15, and up to \$20. It is around \$10 in Adelaide. Patients prescribed large amounts without close monitoring, including private prescriptions and repeats without specified periods before dispensing, are reported as selling many of their tablets.

The Monheit article provides case study examples and suggestions for managing patients seeking addictive medications.

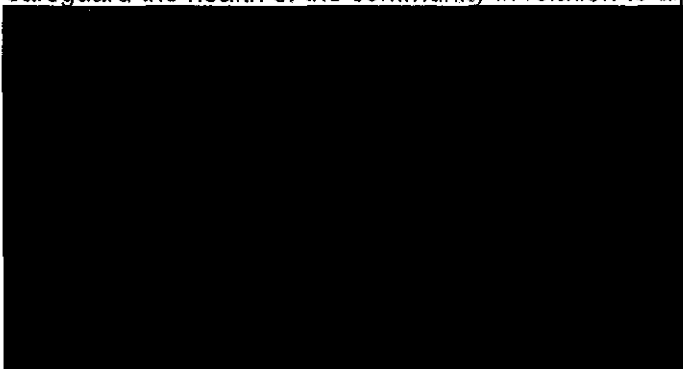
In the NT, while not currently a legal requirement, we also strongly advise that patients prescribed alprazolam or other benzodiazepines should sign a contract agreement as a condition of prescribing, as applies with opiate medications. A template is available at:

http://www.health.nt.gov.au/Environmental_Health/Poisons_Control/Medical_Practitioners/index.aspx

The information in this letter has been provided and endorsed by the Department's Alcohol & Drugs Service and Mental Health Service. Advice and help is available at: Mental Health Services 89 994 988; Tobacco Alcohol & Other Drugs Darwin 89 228 399, Alcohol & Drugs Service of Central Australia 89 517 580; and the 24 hour DACAS-NT (Drug and Alcohol Clinical Advisory Service) 1800 111 092, hosted for NT health professionals by addictions specialists at Turning Point.

http://www.dacas.org.au/About_Us/Consultants.aspx

A copy of this letter will be available on the Department's website. The Department is considering action similar to Tasmania to regulate alprazolam prescribing, and is also working with pharmacists. We are interested in hearing about your experiences and views on the best ways to assist doctors and safeguard the health of the community in relation to alprazolam, and benzodiazepine abuse generally.



Attachments

1. ALPRAZOLAM PRESCRIBING GUIDELINES endorsed by RACGP and RANZCP: Tasmanian Health Department Advisory 2007
2. Warning: Alprazolam(Xanax, Kalma, Zamhexsal): Medical Practitioners Board of Victoria Bulletin June 2009, P 11.

Cc Practice Managers

Warning: Alprazolam (Xanax, Kalma, Zamhexsal)

*This item has been prepared by
the Department of Human Services.*

Recent evidence suggests that alprazolam is more subject to non-medical use, and causes a disproportionately higher level of serious harm, than other benzodiazepines.

Alprazolam is a drug with particularly high potency and short onset of action, which makes it a preferred drug for recreational abuse. As with other benzodiazepines, inappropriately high doses can cause anterograde amnesia. Anecdotal reports suggest that among the benzodiazepines, non-medical use is particularly associated with harmful experiences such as seizures, traffic accidents and crime-related harm.

Alprazolam is now the most commonly reported benzodiazepine among Australian injecting drug users who report injection of benzodiazepines.

Many witnesses giving evidence to the Victorian Drugs and Crime Prevention Committee's *Inquiry into Benzodiazepines and other Pharmaceutical Drugs in Victoria* expressed concerns that alprazolam, when used for recreational purposes, can be particularly dangerous. They commented on its highly addictive qualities. The Senior

Pharmacist at Turning Point Alcohol and Drug Centre commented that for the drug-using population, alprazolam provides the effect they want. Others commented that alprazolam appears to feature more prominently in crime-related activity such as diversion and theft.

The Pharmacy Board of Victoria stated that it was not uncommon for alprazolam (Xanax) tablets (100) to be prescribed and dispensed as private (non-PBS) prescriptions and then on-sold on the street for \$5 per tablet.

The Victorian Interhospital Liaison Group expressed concern that alprazolam is one of the most widely abused of the benzodiazepines and that management of withdrawal was particularly difficult.

Most recently, alarming reports from several Needle Syringe Programs (NSPs) describe the effects of high-dose non-medical use of alprazolam by their clients causing problems of anger and aggression, as well as violent and threatening behaviour, which the users do not remember the next day. During these episodes it is not possible to reason with or calm individuals. Alprazolam tablets are also known as 'angry pills'. Some NSPs report that people affected by high doses will commit crimes such as shoplifting but will be unaware of their surroundings.

When they recover in the police cells they do not remember the actions that led to their arrest. When intoxicated they appear to be more at risk of either committing or being the subject of violence, as well as of falls and other injury as a result of intoxication.

There has been particular concern in Tasmania about prescribing and non-medical use of alprazolam. A circular to pharmacists in that state noted that serious injury and death has resulted from the practice of injecting alprazolam alone, or with other drugs, to produce a heroin-like 'high'.

Alprazolam should only be prescribed when there is a clear indication for its use, after taking into account the risks to the patient and the burden of harm to the community.

The recommendation of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) is that alprazolam has a limited role in the treatment of panic disorder and anxiety. The initial approach should be psychological measures, such as cognitive behavioural therapy. First line drug therapy for panic disorder is stated to be the newer antidepressants, particularly paroxetine and sertraline. Benzodiazepines are listed as second line therapy along with tricyclic antidepressants and the MAOI's. This approach is supported by the PBS approval, which is 'for the treatment of panic disorders where other treatments have failed or are inappropriate'.



THE ROYAL AUSTRALIAN
COLLEGE OF
GENERAL PRACTITIONERS

ALPRAZOLAM PRESCRIBING GUIDELINES

INTRODUCTION

Alprazolam is a short-acting drug in the benzodiazepine class of medications. It is used to treat anxiety disorders and panic attacks. It is usually taken two to four times a day. Alprazolam is sometimes used in the treatment of depression and agoraphobia. Alprazolam may cause drowsiness and affect alertness. Ideally it should only be taken for short periods of time such as 2 to 4 weeks. Benzodiazepines are very effective for treating acute symptoms, but if short acting benzodiazepines such as alprazolam are used long term, the intended effect diminishes with tolerance, there is a high risk of the development of dependency, and the rapidly fluctuating blood levels may exacerbate the symptoms of anxiety disorder.

"Benzodiazepines act more rapidly than antidepressants but are more likely to cause physical dependencies, and such adverse effects as somnolence, ataxia, and memory problems. Antidepressants and benzodiazepines are sometimes used in combination initially with a slow taper from the benzodiazepine after the antidepressant becomes effective".¹

RISKS OF COMBINING ALPRAZOLAM WITH OPIOIDS

Alprazolam, like other benzodiazepines, acts on the central nervous system (CNS). The effects of alprazolam are increased when combined with other central nervous system depressants such as methadone and other opiate related medications.

"Major clinical issues occur with the concurrent use of benzodiazepines and opiates. Benzodiazepines and opiates used together increase the risk of fatal overdose and similarly the use of methadone and benzodiazepines increases the risk of sedation."²

The mortality and harm that is associated with abuse of opioids prescribed in the community is an important emerging issue and associated with that abuse is the concurrent abuse of alprazolam (Alprax®, Kalma®, Xanax® and Zambhexal®). There are also indications that harm levels in the use of this drug are increasing in line with the steadily increasing medical use of opioids.

USE IN PANIC DISORDER

Alprazolam is approved on the Pharmaceutical Benefits Scheme (PBS) 'for the treatment of panic disorders where other treatments have failed or are inappropriate'.³

Consideration needs to be given to whether the patient is suffering from panic disorder and not a generalised anxiety disorder, or from anxiety symptoms generally, including those associated with drug abuse. Whilst isolated panic attacks are common, panic disorder is uncommon. It is quoted as affecting 2 to 3% of the population in a 12 month period and is 2 to 3 times more prevalent in women than men.

¹ The Merck Manual 18th Edition, 2006, Page 1677;

² National Comorbidity Project - Comorbidity of mental disorders and substance use; National Mental Health Strategy; National Drug Strategy.

³ Schedule of Pharmaceutical Benefits August 2006 - Psycholeptics; Alprazolam

Benzodiazepines

"The initial approach for the prophylaxis of panic disorder should include psychological measures such as cognitive behavioural therapy (CBT). While these will suffice for some patients, others will need drugs as well. Some patients initially do not relate to a psychological approach and cannot use CBT. They should be commenced on a first line pharmacological drug, with CBT added later if possible. Regarding effectiveness, the number needed-to-treat to get one person panic free is 3 for CBT and 5 for medication. Pharmacotherapy for panic disorder may need to be continued for 6 to 12 months in the first instance"⁴

First line therapy is stated to be "newer antidepressants particularly paroxetine and sertraline".⁵ Benzodiazepines are listed as second line therapy along with tricyclic antidepressants and MAOI's.

The bi-national Committee of Psychotropic Drugs and Other Physical Treatment (COPDOPT) take the view that there is some, be it small, evidence-based support for the use of alprazolam for short periods. In using it consideration should be given to the fact that:

- the enduring benefit is small
- cognitive and motor side-effects of long term use must be considered
- the relatively greater development of tolerance and problems with withdrawal in patients using short acting agents such as alprazolam.

In the case of drug abuse very careful consideration needs to be given to the use of benzodiazepines, with diazepam being a preferred treatment for anxiety associated with drug withdrawal. Ideally such patients should be referred to an Alcohol and Drug specialist/services.

ALPRAZOLAM ABUSE

Pharmaceutical Benefits Scheme data suggest that alprazolam prescribing in Tasmania is approximately 100% higher than the national average. Similarly the use of opioids in Tasmania is approximately 50% higher than the national average. The reported use of intravenous alprazolam in conjunction with methadone to achieve a "heroin" like high is of particular concern.⁶ In Tasmania there is an illicit drug problem associated with legally prescribed drugs and very little heroin. The practice of intravenously injecting alprazolam with methadone presents a very serious risk of overdose.

Consistent with other jurisdictional arrangements, alprazolam is listed as a declared restricted substance under the Tasmanian Poisons (Declared Restricted Substances Order 1990). This requirement means that prescriptions dispensed in Tasmania must be written by prescribers registered in Tasmania. It also places other conditions on its supply by the dispensing pharmacist as a declared restricted substance. Possession except in accordance with a legal prescription is illegal and prescribers cannot prescribe this for drug dependent persons receiving Schedule 8 medications unless they are the holder of an authority issued under S22 of the *Alcohol and Drug Dependency Act 1968* for those medications.

(Refer – DHHS - Legal requirements for the prescribing of Alprazolam) July 2007

⁴ Therapeutic Guideline: Psychotropic Version 5 Melbourne 2003, Page 176

⁵ Therapeutic Guideline: Psychotropic Version 5 Melbourne 2003, Page 176

⁶ R Bruno; Tasmanian Drug Trends 2006 – Findings from the Illicit Drug Reporting System (IDRS) NDARC .

Alprazolam prescribing

A resource for South Australian prescribers

This resource assists medical practitioners to:

- > Critically examine the need for prescribing alprazolam in their medical practice.
- > Become familiar with current concerns with alprazolam abuse amongst vulnerable populations.
- > Identify risk factors that should trigger patient referral to specialist services.
- > Seek help from regulatory and clinical information sources if requested to prescribe alprazolam.

Introduction

Alprazolam is a rapid-onset, short-acting benzodiazepine indicated for treatment of anxiety disorders and panic attacks. Ideally alprazolam should be prescribed for short periods, such as two to four weeks. In South Australia alprazolam abuse especially in drug dependent populations is being reported more frequently. This is similar to other Australian jurisdictions. Large pack sizes and a sought-after pharmacological profile makes alprazolam the benzodiazepine of choice amongst drug dependent populations.

Concerns with prescribing alprazolam

Significant consequences for both patient and prescriber may flow from alprazolam abuse.

In the worst cases, excessive doses of alprazolam taken alone or in combination with other benzodiazepines, opioids, or alcohol may result in death. Other concerns include:

- > initiation or maintenance of benzodiazepine dependence
- > interference with opioid pharmacotherapy treatment
- > risk of severe benzodiazepine withdrawal syndrome and seizures
- > increased risk of motor vehicle accidents (whether as driver or pedestrian).

For prescribers, concerns include the prescriber:

- > becoming known amongst drug-dependent populations as an alprazolam 'script doctor'
- > contributing to the already substantial illicit trade in pharmaceutical drugs
- > placing themselves at professional, civil, or criminal risk for prescribing to known dependent persons.



Benzodiazepines

Guidance on prescribing alprazolam

1. Have a clear and documented treatment plan, informed by:
 - > agreed treatment goals
 - > appropriate patient selection
 - regular patient to practice [never on the first appointment]
 - treatment is supported by a specialist
 - patient is willing to engage in treatments other than benzodiazepines (eg antidepressants, CBT).
 - > firm diagnosis
 - > justifiable rationale for prescribing alprazolam not based on patient requests for the drug
 - > strict adherence to frequency and dose. [ie the patient should not "run out" ahead of schedule]
 - > when withdrawing alprazolam, a gradually reducing dose should be prescribed to avoid a withdrawal syndrome. Any reduction should not exceed 0.5mg every three days.¹
2. Active communication with:
 - > other treatment providers involved in the patient's care (doctors, pharmacists, Assessment and Crisis Intervention Service)
 - > health authorities (Drugs of Dependence Unit, Medicare Australia).
3. Regular urine drug screens to detect undisclosed drug use.
4. Specialist referral where necessary, for example:
 - > unclear diagnosis
 - > drug-seeking behaviour
 - > excessive or problematic consumption of:
 - benzodiazepines
 - alcohol
 - opioids
 - > active treatment for drug dependence / intravenous drug use (opioid pharmacotherapy)
 - > past history of drug dependence / misuse
 - > young patient
 - > past or current injecting drug use [check their arms for injection sites!]
5. Regular follow up and responsible information-sharing with the patient and members of the treatment team.

Signs of potential misuse of alprazolam

- > Reports of lost / stolen prescription or medication
- > Patient specifically requests drug by name
- > Patient exhibits demanding or intimidating behaviour
- > Presenting intoxicated
- > New patient to clinic and no previous medical reports available
- > Signs of recent or past injecting
- > Patient unwilling to engage in treatment as outlined in the Guidance



Benzodiazepines

Use of alprazolam in panic disorder

Alprazolam is approved on the Pharmaceutical Benefits Scheme for the treatment of panic disorders where other treatments have failed or are inappropriate.²

Prescribers should exclude from the differential diagnosis a Generalised Anxiety Disorder, Social Phobia, Obsessive-Compulsive Disorder, Post Traumatic Stress Disorder, anxiety symptoms associated with drug misuse, or anxiety due to a general medical condition.³

Whilst isolated panic attacks are common, panic disorder is uncommon. The reported lifetime-prevalence in the developed world is considered between 1.4% and 2.9%, more common in females.⁴ The point-prevalence in Australia has been identified as low as 0.7%.⁵

"First line treatment for Panic Disorder is with non-pharmacological approaches. Education about the disorder, in particular explaining the way in which the panic attack produces physical symptoms, is essential. Breathing control strategies... and relaxation strategies are also important first steps.

Cognitive behavioural therapy (CBT) is the treatment of choice for panic disorder. There are several versions of this used for panic disorder. The most commonly used is panic control treatment, which involves exposure to deliberately induced symptoms, together with techniques (such as controlled slow breathing) for controlling symptoms and reattribution of symptoms to benign causes (eg palpitations are not due to cardiac arrest)".⁶

When CBT is not available or ineffective, pharmacological treatment may include (in order of preference):

- > SSRIs / SNRIs
- > TCAs
- > MAOIs
- > some benzodiazepines (clonazepam, alprazolam)

Pharmacological treatments should ideally be used for not more than 6 – 12 months, eventually being reduced and ceased. It is acknowledged, however, that some patients may require ongoing treatment with these medicines.

Contacts for help

Drugs of Dependence Unit: 1300 652 584. Office hours.

Medicare Australia: 1800 631 181 – Prescription Shopping Program requires prior registration see <http://www.medicareaustralia.gov.au/provider/pbs/prescription-shopping/index.jsp>.

Drug and Alcohol Clinical Advisory Service: 8363 8633. A 24 hour 7 day per week advisory service for clinicians seeking advice on management of people with alcohol and drug related problems.

Recommended further reading

Royal Australian and New Zealand College of Psychiatrists Clinical Practice Guidelines Team for Panic Disorder and Agoraphobia, 'Australian and New Zealand clinical practice guidelines for the treatment of panic disorder and agoraphobia' (2003) 37 *Australian and New Zealand Journal of Psychiatry* 641.



Government
of South Australia
SA Health

Benzodiazepines

References

1. Full Product Information, Xanax (alprazolam), Therapeutic Goods Administration approved 31 July 2007.
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5. G Andrews, W Hall, M Teesson, and S Henderson, 'The Mental Health of Australians' (1999) Commonwealth Government, Department of Health and Aged Care.
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Acknowledgement

Drug and Alcohol Services South Australia thanks the Tasmanian Department of Health and Human Services for allowing the reproduction of *Alprazolam Prescribing Guidelines*, and New South Wales Health, Pharmaceutical Services Branch, for allowing reproduction of *Recognising and Handling Patients Liable to Abuse Benzodiazepines: Notes for Medical Practitioners*.

Endorsement

This fact sheet has been endorsed by the Royal Australian College of General Practitioners and the The Royal Australian and New Zealand College of Psychiatrists.



The Royal Australian
College of General
Practitioners



The Royal
Australian &
New Zealand
College of
Psychiatrists

For more information

Drugs of Dependence Unit
Telephone: 1300 652 584
Facsimile: 1300 658 447

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of South Australia
SA Health

Benzodiazepines

[REDACTED]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601
Email: SMP@health.gov.au

Dear Sir/Madam,

Re Scheduling proposal to reschedule benzodiazepines from Schedule 4 (S4) to Schedule 8 (S8)

I am very concerned at this rescheduling proposal and the consequences it will have on a number of sectors, particularly the pharmacy and aged care sectors

[REDACTED]

In order to meet routine dispensing requirements, my pharmacy generally keeps in stock the following quantities of benzodiazepines:

[REDACTED]

If benzodiazepines as a class are rescheduled to S8, this will have a significant administrative burden for my pharmacy as well as for the residential facilities I service. In order to meet my responsibilities as a pharmacy owner, I would need to install a significantly larger safe to accommodate the volume of benzodiazepines as well as the S8 medicines I already carry.

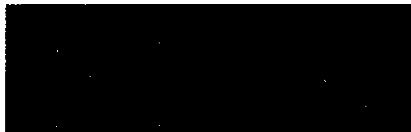
Similarly, the residential facilities I service will have to implement changes to address any reschedule. They will have to review their storage and recording arrangements for these medicines as well as the administration of the medicines to the residents. S8 medicines require greater intervention from higher level nursing staff than S4 medicines. As such, this change will have both a staff resourcing and financial impact on these facilities. I am concerned that for them to meet legislative and administrative requirements, given their limited funding, they may have to direct staffing from other service areas, to the detriment of the care of the resident.

Benzodiazepines

Noting the level of doctor-shopping and pharmacy-shopping and uncontrolled abuse/misuse that currently occurs with 58 medicines such as oxycodone, I do not believe that rescheduling benzodiazepines will accomplish the desired outcome. Particularly as I do not believe there is a class issue. It is my understanding that the issue is predominantly with Alprazolam, and that it is not necessarily a nationwide issue but problematic in certain locations. Acknowledging there is a need to address any issue of medicine abuse or misuse, I feel there are more appropriate mechanisms to address this issue, such as real-time monitoring, benzodiazepine contracts and staged supply services. If the issue is for specific benzodiazepines in specific regions, I suggest that Medicare Locals could be tasked with working with jurisdictional Health Departments and professional organisations to look at implementing some of these measures.

I strongly urge the Committee to recommend that benzodiazepines remain in Schedule 4.

Yours sincerely

A solid black rectangular box used to redact the signature of the sender.

Benzodiazepines



17th January, 2013

The Secretary
Medicines and Poisons Scheduling
GPO Box 9848
Canberra ACT 2601
Email: SMP@health.gov.au

Dear Sir/Madam,

Re: Public Submission – under Regulation 42ZCZK of the Therapeutics Goods Regulations 1990 – ACMS Meeting March 2013

In reference to the pre-March 2013 Scheduling Meeting notice inviting public comment, Sanofi notes the scheduling proposal for benzodiazepines as outlined below:

Proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8

At the request of the Paediatric Medicines Advisory Group to address a recognized unmet medical need, Sanofi has supported an application for clobazam for use in the orphan indication paediatric partial refractory epilepsy as outlined below. The product has been used 'off label' for this purpose for many years in Australia, but has been approved in other major territories including New Zealand for more than two decades for this use. The application is currently under evaluation by the TGA:

Children (4 years of age and over)

As adjunctive therapy in patients with partial refractory epilepsy who are not adequately stabilized with their current anticonvulsant therapy.

The intended treatment population are children for whom all existing treatment options have failed. Usage will be initiated by specialists and is intended to be short term and closely monitored.

In light of the intended use in this rare condition which is significantly different to the potential risks when used for anxiety or sleep disturbances, Sanofi does not consider that rescheduling is appropriate, on the basis it adds complexity to making treatment available to those who have a significant medical need. Sanofi would appreciate being advised of the Committee's consideration with the opportunity for further comment, if appropriate.

Yours faithfully,

A large black rectangular box redacting the signature and name of the representative.

Benzodiazepines

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

To whom it may concern,

Re: Proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8.

I was most concerned when I heard of this submission and the impact it will have on the staff who work in Aged Care.

Benzodiazepines are commonly used drugs in Aged Care Facilities.

If Benzodiazepines are rescheduled from Schedule 4 to Schedule 8 this will result in a major increase in time required for Registered and Enrolled Nurses to check these drugs and also to administer them. (Schedule 8 drugs must be given and checked by 2 staff).

This will largely impact on the time that RN/EN staff have to provide care to the residents.



Benzodiazepines

Think Clinical Services
Phone 07 3216 4888
Fax 07 3318 7667
clinicalmanager@thinkpharmacy.com.au

14 February 2013

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Dear Sir / Madam

Please see below Think Clinical Services response to the recent notification inviting public submissions under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990 re: the proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8, for consideration by the ACMS.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. Proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Medicines Scheduling (ACMS)

Substance/s	Scheduling proposal
Benzodiazepines	Proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8.

Comment on the proposed amendment: Proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8, for consideration by the ACMS – 14th February 2013.

We would appreciate your consideration of our comments below, based on our experience in the aged care industry, particularly Qld. These comments were based on our experience in both a clinical and supply role of pharmacy services to aged care facilities (ACFs) as well as the gathering of comments from Directors of Nursing at some of our ACFs. In addition there is an attached letter of comment from one of our ACF.

If all benzodiazepines are to be rescheduled from S4 to S8:

1. The physical amount of extra stock to be held in existing safes (as described in the Qld Poisons Regulations) in aged care facilities would pose a significant problem. Most ACFs already struggle to fit current stocks of Controlled Drugs into their safes. This problem exists whether medications are compliance packed or in original packs. For compliance packed medications, all S8 medications would be required to be packed per drug, per resident, further increasing the physical size of the medications to be stored in the safes.
2. It has already been established that compliance packed medications in aged care facilities, reduce medication errors. With rescheduling benzodiazepines, because extra compliance packed medications will currently not fit into the safe (as described above), the use of original packs may again be considered, thus potentially increasing medication administration errors, impacting on resident safety.
3. With rescheduling, there will be an increase in the time taken for medication administration rounds by registered staff at the facility, in view of the extra documentation required and the repeated access to the Controlled Drug safe (as a separate drug storage area to the commonly used secure drug trolley). Once again, Qld Poisons Regulations dictate that S8 medications must be securely stored in a safe that meets the standards described within these Regulations. This impacts on timely administration of medications, already an issue in aged care, particularly with morning rounds of medication administration.

If the motivation for the rescheduling is concern over the potential misuse of benzodiazepines

1. Compliance packed medications can reduce access to substances of abuse/dependence. This supports the packaging of regular benzodiazepines. Consideration could be given to the recording of all prn doses of benzodiazepines in a controlled drug register and the packing of these prn doses into single dose sachets/ packs to further reduce potential for abuse. This procedure is currently being used in one of our ACFs and has significantly reduced both the potential for misuse and the actual use of prn doses of benzodiazepines, ensuring care staff consider alternative non-drug options in the case of prn benzodiazepines. This has improved both potential for misuse and patient care and has significantly reduced the number of prn doses of benzodiazepines administered to residents.

Benzodiazepines

2. Consideration may be given to a mandatory review of the use of regular benzodiazepines every 6-12 months to assist in ensuring the judicious use of benzodiazepines. This review could be undertaken by an accredited clinical pharmacist as part of the current RMMR contracts, preferably with GP RMMR referral, but perhaps also as a Pharmacist Only Review.

For Reference:

The table below provides data on the total number of benzodiazepines packed for aged care residents using Think Clinical preferred dose administration provider for the month of December 2012.

1. Data collated for the period of 1st December 2012 – 31st December 2012
2. The total number of residents receiving packed medication for the period was 24, 486 residents
3. The total number of medications packed for the period was 8, 541, 878
4. The total number of Benzodiazepines packed for the period was 240, 351
5. The percentage of Benzodiazepines packed to all medication packed for the period was 2.81%

Brand Name	Form	Strength	Generic Name	VIC	NSW	QLD	Total
ALEPAM	TAB - TABLETS	15mg	Oxazepam	12,129.50	1,498.00	32,784.25	46,411.75
ALEPAM	TAB - TABLETS	30mg	Oxazepam	3,257.75	1,340.00	15,436.50	20,034.25
ALODORM	TAB - TABLETS	5mg	Nitrazepam	1,048.00	685.50	6,807.75	8,541.25
ANTENEX	TAB - TABLETS	2mg	Diazepam	1,310.25	1,166.00	9,024.25	11,500.50
ANTENEX	TAB - TABLETS	5mg	Diazepam	2,674.50	2,049.50	21,365.00	26,089.00
ATIVAN	TAB - TABLETS	1mg	Lorazepam	670.50	1,022.00	2,820.00	4,512.50
ATIVAN	TAB - TABLETS	2.5mg	Lorazepam	84.00	56.00	505.50	645.50
LEXOTAN	TAB - TABLETS	3mg	Bromazepam	98.00	87.50	213.50	399.00
LEXOTAN	TAB - TABLETS	6mg	Bromazepam	14.00	70.00	268.00	352.00
MOGADON	TAB - TABLETS	5mg	Nitrazepam	28.00		161.00	189.00
MURELAX	TAB - TABLETS	30mg	Oxazepam			547.50	547.50
NORMISON	TAB - TABLETS	10mg	Temazepam	63.00	171.50	674.00	908.50
PAXAM	TAB - TABLETS	2mg	Clonazepam	220.50	133.00	4,099.50	4,453.00
PAXAM	TAB - TABLETS	500mcg	Clonazepam	1,581.00	1,563.50	7,854.00	10,998.50
RIVOTRIL	TAB - TABLETS	500mcg	Clonazepam			102.00	102.00
SEREPAX	TAB - TABLETS	15mg	Oxazepam	10.50	8.75	516.25	535.50
SEREPAX	TAB - TABLETS	30mg	Oxazepam	45.00	52.50	471.50	569.00
TEMAZE	TAB - TABLETS	10mg	Temazepam	17,563.50	13,188.00	71,338.50	102,090.00
TEMTABS	TAB - TABLETS	10mg	Temazepam	28.00	49.00	994.00	1,071.00
VALIUM	TAB - TABLETS	2mg	Diazepam		28.00	59.50	87.50
VALIUM	TAB - TABLETS	5mg	Diazepam			251.50	251.50
VALPAM	TAB - TABLETS	2mg	Diazepam			28.00	28.00
VALPAM	TAB - TABLETS	5mg	Diazepam			35.00	35.00
Total Benzodiazepines packed December 2012				40,826.00	23,168.75	176,357.00	240,351.75
Total - All medications packed December 2012*				1,340,535.25	1,312,655.75	5,888,687.00	8,541,878.00
Percent of Benzodiazepines packed December 2012				3.05%	1.77%	2.99%	2.81%
* 24, 286 total residents were packed for in December 2012							

Benzodiazepines

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

17th January 2013

To Whom It May Concern,

RE: Proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8

As the Director of Nursing of a 108 bed Residential Aged Care facility I wish to make comment on the proposed change regarding the re-scheduling of Benzodiazepines from S4 to S8.

Benzodiazepines are a group of drugs used in Residential Aged Care facilities that are used for minor tranquillisers to help the elderly people with anxiety or sleep problems. The use of Benzodiazepines in RACF is prescribed guardedly by the General Practitioners and prescribed only when all other options are exhausted in terms of non-pharmacological interventions. Its use is monitored comprehensively by the pharmacists and administered by competent nursing staff and or care staff under the supervision of registered nursing staff.

All medicines are stored safely and strict security policies are adhered to in preventing access to unauthorised persons. In our RACF most of the medications are pre-packed in sachets and ordered as a regular medication and for this reason there is limited medication stock of large quantities of any medication including benzodiazepines. Having the medications pre-packed for individual use ensures a tighter safer storage of medication and also reduces the potential of medication errors and or tampering of medication.

Currently our facility has two (2) large DD safes for the storage of S8 medications accompanying three (3) DD registers. All S8 medications are checked three times per day and once a week by the Director of Nursing to ensure safety and security of all S8 medications. This process is an extremely taxing on nursing staff in terms of time and the reduction of clinical care not to mention the additional requirement of two nurses for the administering of all individual S8 medication across two buildings to three service areas.

Should the re-scheduling of Benzodiazepines as an S8 drug be introduced, it would certainly create an enormous impact on staff resources, reduction in care hours and create a further reduction in space and storage of medicines which already is an issue in aged care.

The scripting of benzodiazepines will become a problem if the national chart system is introduced; because individual prescriptions will still be required for S8's which would then have the potential to include all benzodiazepines as well.

From a personal and professional perspective I would like to make comment that in Australian RACF's we are now painstakingly regulated to ensure best practice and safe practices and over the seven years in working in aged care I have only once come across tampering of medication by a staff member and the facility was able to recognise the incident promptly due to sound policies; action was taken and problem resolved. I strongly support the notion of not over regulating the S4 medicines as I believe there would be little gain in improvement of the current security, safety and efficiency practices of the Schedule 4 and Schedule 8 medicines management.

I trust my comment will assist in decision making process of re-scheduling of S4 Benzodiazepines.

Thanking you.

██████████
██████████

Benzodiazepines

I am a registered pharmacist with 9 years of practice in South Australia. I work on several Medication Advisory Committees. And my practice includes community pharmacy, nursing home and home medication reviews.

Rescheduling of BZDs to S8 seems a blunt tool to further Quality Use of Medicine. It is a bureaucratic and not educational approach that will restrict access to a useful and often clinically appropriate therapy. I cannot help feeling that it is implied that doctors may not always be competent in prescribing BZDs. Targeted education of health professionals is much preferred, possibly based on a ratio of PBS BZD scripts versus all other PBS prescriptions. Rescheduling is in my view unlikely to halt the over prescribing of a few doctors but will make practice more difficult for the vast majority of responsible prescribing doctors.

I would also not expect illegal diversion of BZDs to be greatly reduced based on experience with other schedule 8 drug such as Oxycontin.

Should this be implemented I wish for an objective quantitative measures to be in place, such as counting not just PBS prescription but all BZD prescriptions. Many BZD prescriptions can be dispensed as private prescriptions and do not turn up in PBS statistics and the number of these scripts would be difficult to measure. Perhaps one needs to look at wholesaler data as a surrogate marker of BZD use in the community. In addition a comparison needs to be made of BZD-related hospital admissions, ADR and motor vehicle accidents before and after the intervention.

Perhaps try this in a single state first and obtain solid evidence first before making a nation-wide decision.

In terms of the logic: there are more hospital admissions related to warfarin and insulin. Should these be made S8?

There are more people in the community who are dependent on nicotine and EtOH and these drugs are self-selected and unscheduled. Harm associated with these readily available drugs dwarfs any harm from BZD use yet little is done about this problem.

I suggest leaving BZD S4 and perhaps target by education doctors who based on PBS claim data seem to prescribe an excessive amount of BZDs (I would estimate no more than 5% of all GPs).

Thank you

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

The Secretary
Scheduling Secretariat
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CANBERRA ACT 2601
Facsimile: 02 6289 2650

Email: SMP@health.gov.au

**Re: Invitation for public comment - ACMS and ACCS meetings, March 2013
Proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8.**

Dear Secretary,

[REDACTED] refers to the pre - March 2013 scheduling meeting notice inviting public comment and wish to comment specifically on the application to reschedule benzodiazepines from Schedule 4 to Schedule 8.

We appreciate the opportunity to comment on this matter, albeit being unaware of the reasoning behind the proposal to reschedule to Schedule 8 status.

Discussion on Proposal

Benzodiazepines have long been used to treat a wide variety of disorders for different patient populations, and their safety profiles, risks and benefits are well established and documented.

Benzodiazepines are the most commonly prescribed psychoactive drug in western societies and their uses include: anxiety disorder, panic disorder, sleep disorders, depression, epilepsy, anaesthesia and intensive care, acute alcohol withdrawal and psychiatric emergencies.¹

Despite concerns regarding physiologic dependence, withdrawal, and possible abuse potential, benzodiazepines have a legitimate place in therapeutics and [REDACTED] strongly believes that these concerns are best managed by physician guidance, quality patient focused care and careful prescribing. In addition, [REDACTED] believes that the inclusion of benzodiazepines in Schedule S8 would be unlikely to address these issues and will negatively impact patients who truly benefit from these drugs.

Furthermore, adequate and clear guidelines addressing practical strategies for appropriate prescribing and managing patients on benzodiazepines are lacking. [REDACTED] believes that the development of such guidelines would best address the sometimes complex clinical management of patients with conditions such as anxiety, depression and insomnia and the eventual withdrawal of benzodiazepines in such patients.

The stringent approach to prescribing benzodiazepines adopted by some healthcare professionals has led to the substitution to alternative medicines that may have reduced efficacy and substantial safety concerns, such as with zolpidem, which also has the potential for abuse and remains a Scheduled 4 prescription medicine.²

[REDACTED]

██████████ feels that there is a need for a more balanced approach to prescribing benzodiazepines, which involves the assessment of risk and benefits, to ensure that patients who would truly benefit from these agents are not denied appropriate treatment. ██████████ believes that the rescheduling to S8 would oppose the balanced approach required for the appropriate prescribing of benzodiazepines to patients who would legitimately benefit from treatment.

Furthermore, stronger prescribing restrictions could result in frustration and incomplete treatment of patients who are handed back to the GP by their specialist, if the GP refuses to prescribe the benzodiazepine required for continuation of their treatment.

Current prescribing and use of benzodiazepines.

Benzodiazepine use remains an important therapeutic option worldwide. However, Australian PBS data shows an overall reduction in prescribing of benzodiazepines, except for alprazolam.³

In an assessment of prescription drug misuse, it was found that in Australia, the most abused drugs are oxycontin and alprazolam, a short acting benzodiazepine.² As the benzodiazepines differ in half-lives, safety, indications for use and abuse potential, it would be unreasonable to group them together and impose the same restrictions on all the benzodiazepines. Also, we note that the Schedule 8 status of oxycontin has not addressed the high abuse rate that it holds. Rather, we strongly believe that practical guidelines with clear strategies for managing patients who may be abusing prescription medicines would be the best approach to tackle these issues.

A recent meta-analysis showed that a simple intervention, such as a letter or single GP consultation, resulted in a substantial reduction in benzodiazepine use in long-term users.⁴ These results demonstrate that it's the patient care and strategies for quality use of medicines that make the difference.

As with all medicines, the physician together with the patient should assess the risks and benefits of benzodiazepine treatment relevant to the patient's individual clinical situation. Once, the decision is made to use a benzodiazepine, a treatment plan that ensures the shortest treatment duration possible with the lowest dose possible, should be agreed upon.

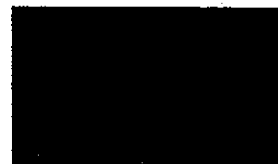
Conclusion

██████████ supports the quality use of medicines as the main strategy for the appropriate prescribing of benzodiazepines - better outcomes are achieved when the physician discusses and devises a treatment plan in conjunction with the patient. Treatment often involves multiple interventions from various healthcare professionals; therefore, the GP becomes an integral part in co-ordinating patient treatment.

In general, benzodiazepines should be prescribed for short-term use only, however, there is a limited role for long-term use in some patients, and these patients should be managed with care.

There is a need for more useful resources to help GPs review the use and eventual withdrawal of benzodiazepines by their patients. These resources would best address the concerns around benzodiazepine use.

Benzodiazepines are not included in Schedule I, Schedule II or III of the WHO Convention on Psychotropic Substances 1971, therefore rescheduling to S8 would not be consistent with this.



Benzodiazepines

For healthcare professionals, especially pharmacists, there would be additional costs introduced for storing and dispensing of benzodiazepines if rescheduled to Schedule 8 status.

Finally, the long standing and established history of benzodiazepine availability and use, does not warrant it's rescheduling to Schedule 8 status.

[REDACTED] therefore considers that benzodiazepines should remain as Schedule 4. We hope the above comments are useful in the consideration of this matter, and look forward to hearing the outcome.

Yours sincerely

[REDACTED]

[REDACTED]

Benzodiazepines

References:

1. Sim MG, Khong E, Wain TD. The prescribing dilemma of benzodiazepines. Aust Fam Physician. 2007 Nov;36(11):923-6.
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3. Department of Health and Aging. Australian Statistics on Medicines. Available at <http://www.health.gov.au/internet/main/publishing.nsf/content/pbs-asm-2009> [Accessed 09 January 2013]
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MEDITRAX SUBMISSION TO TGA - PROPOSED RE-SCHEDULING OF BENZODIAZEPINES FROM S4 TO S8

Meditrax is a company who employs a team of Accredited Pharmacists providing Medication Review and QUM services to Residential Aged Care Facilities, mainly in New South Wales. We service over 300 Aged Care Homes. We are committed to the provision of quality professional services to Aged Care Facilities and aim to work in partnership with facilities to improve medication management and resident outcomes through comprehensive medication reviews and a diverse range of Quality Use of Medicine Services.

Meditrax has been contacted by some facilities who have expressed concerns regarding the proposed re-scheduling of benzodiazepines. We have encouraged facilities to make separate submissions to TGA and have emailed to facilities some information to consider regarding the potential impact of the proposed re-scheduling.

Meditrax pharmacists continue to encourage reduction of benzodiazepine prescribing by the use of the Medication Review process, the provision of education sessions to care staff and specific recommendations to prescribers based on current guidelines. The proposed re-scheduling of benzodiazepines may complement this process but also has the potential to negatively impact on resident care if adequate preparation and planning is not implemented.

In response to the anticipated issues, Meditrax will provide ongoing support and education to Aged Care Facilities to reduce the likely impact of proposed re-scheduling. Meditrax will work with facilities and doctors to encourage gradual withdrawal of benzodiazepines where appropriate in accordance with quality use of medicines guidelines, highlighting the potential benefits to residents of withdrawal and providing supporting educational material to implement withdrawal programmes.

The following points summarise potential issues pharmacists at Meditrax have identified:

1. Alternate agents

- Doctors may prescribe alternate agents with sedative effects (eg antipsychotics, antidepressants, sedating antihistamines) for patients with insomnia and/or anxiety disorders which may be inappropriate and also associated with potentially harmful adverse effects, particularly in the elderly.
Close monitoring of the prescribing of such agents may be appropriate should re-scheduling of benzodiazepines take place, as well as appropriate education provided to prescribers regarding the risks of such agents in the elderly.

2. Non-benzodiazepine hypnotics

- The proposed rescheduling at this stage does not include the non-benzodiazepine hypnotic agents or 'z' drugs, namely Zolpidem (Stilnox®) and Zopiclone (Imovane®). Prescribing of these agents may increase if they remain S4 if benzodiazepines become S8, but they have similar risks and adverse effects as the benzodiazepines particularly in the elderly.
If Benzodiazepines are re-scheduled, re-scheduling of these agents to S8 is suggested to also be considered.

3. Continuity of supply to residents in Aged Care Facilities

- Supply of benzodiazepines to residents of Aged Care Facilities may be interrupted with potential for withdrawal symptoms if prescriptions are not promptly provided to supplying pharmacies as legally required for S8's to be dispensed. Elderly residents who have been taking benzodiazepines for several years may be particularly susceptible to withdrawal symptoms. The necessity for prescriptions to be written without the ability for owing supplies to be dispensed may increase the demands and workload for doctors as well as supplying pharmacies, with potential negative impact on patient outcomes if timely supply is not carried out.

A transition period may be required to reduce these risks and as many people may have a long term dependency, provision for continuity of supply will be important.

4. Increased Workload in Aged Care Facilities and Supplying Pharmacies

- There will be a likely increase in workload of RN's due to required recording of receipt and administration in the S8 register of benzodiazepines. In most facilities and in particular High care facilities there is also a requirement for witnessing the whole process of administration and recording of S8s. This already takes significant time and this time is not recognised in the Aged Care Funding Instrument.
- There may also be a likely increase in care staff workload as they may be required to provide additional support during withdrawal of benzodiazepines with some residents, and to manage non-drug strategies for promoting sleep on an ongoing basis.

Concerns are that the quality of care to residents may decline unless adequate financial support can be provided to facilities to offset increased staffing requirements that may result with this change to scheduling.

Pharmacists do currently get extra re-imbursement for recording of S8 Pharmaceutical Benefits prescriptions through the Pharmaceutical Benefits Scheme.

Aged Care Homes also need to be recognised.

5. Funding to Aged Care Facilities

- Current ACFI (Aged Care Funding Instrument) does not recognise insomnia as a separate condition and no funding is available to provide non-drug measures for management for which there is good evidence of effectiveness.
- ACFI also does not provide funding for the time required to record S8 administration in the drug register as legally required in high-level care facilities as stated. Consequently resident care may be compromised due to reduced 'hands on' care able to be provided by current RN staffing at Aged Care Facilities.

Meditrax seeks the support of the TGA to collaborate with Aged Care Peak Bodies and administrators of ACFI to make appropriate adjustments to funding and support to facilities.

6. Low Care Facilities

- While low care facilities are not legally required to record S8 drugs, best practice guidelines and Meditrax recommend recording of at least regular non-blister packed S8 drugs and all PRN S8 drugs, which reduces the risk of misappropriation and possible abuse. As many benzodiazepines are prescribed on a PRN basis, increased recording

Benzodiazepines

requirements may also significantly impact low care facilities and reduce the time care staff are able to provide 'hands on' care to residents. Low care facilities may choose to no longer follow recommended best practice guidelines which may increase the risk of misappropriation and abuse of PRN S8 drugs which would negate the reduced risks of abuse by transferring benzodiazepines to S8.

Meditrax seeks the support of the TGA to collaborate with administrators of ACFI to make appropriate adjustments to funding and support to all Aged Care Facilities.

7. Storage in Aged Care Facilities

- If benzodiazepines are rescheduled to S8, some high care facilities may have inadequate storage space in S8 cupboards.

Although there may be some reduction in benzodiazepines prescribed, it is unlikely to cease and to provide adequate support to facilities regarding increasing storage requirements anticipated from re-scheduling of S8's may be appropriate – This may include an extended period of time to implement the change in storage.

Summary

Meditrax requests that these points are recognised and considered as there may otherwise be a negative impact on patient outcomes in Residential Aged Care Facilities should benzodiazepines be re-scheduled.

Meditrax would be happy to provide further information on request and/or contribute to any further discussion regarding this issue.

Benzodiazepines

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

January 17th 2013

Re: Proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8.

Dear Sir / Madam,

I write to lodge my concern at the proposed rescheduling of benzodiazepines from Schedule 4 to Schedule 8.

The impact upon resourcing in Residential Aged Care Facilities would be overwhelming to many services and providers.

Staff in this industry are already under enormous pressure and time constraints.

Increased levels of care needs of residents in permanent residential care, demands that Registered Nurses be available to review, monitor and address direct care and offer supervision to staff.

Removing Registered Nurses from the floor for additional periods of time for the management of increased numbers of Schedule 8 medications would be detrimental to the delivery and oversight of care.

Given the recent publicity and interest in psychotropic medications within the aged care sector, I am surprised that these drugs are not under heightened scrutiny, is rescheduling of this class under discussion?

The views expressed are my own opinions and not necessarily those of the organisation for which I work, therefore I ask you to respect confidentiality with regard to my name and position.

Benzodiazepines



The impact on our Aged Care Facility would be large

- We have one Registered nurse on duty per shift and while they attend to S8 medications it would be extremely time consuming to add to this the S4's.
- you would be required to take an additional staff member(who are already busy and do not have extra time) off the floor to administer the S4.
- Our current S8 safes are not large enough to hold surplus S4's.
- Currently S4's are monitored/ restricted by GP's through prescription, authorities etc.
- Currently our practice for S4's is safe and reliable, with regular S4's being packed and prn S4's locked away and only accessed by RN's



Victorian Institute of Forensic Medicine

Division of Clinical Forensic Medicine
11 Moore Street, Southbank Victoria, Australia 3006
MONASH University

The Secretary

Scheduling Secretariat

GPO Box 9848

Canberra ACT 2601

16 January 2013

**Re: proposed amendment to the Poisons Standard referral to scheduling advice:
Submission under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990.**

Substance	Scheduling proposal
Benzodiazepines	Proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8

This submission strongly supports the proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8. Benzodiazepines are well known to be addictive drugs yet are available on prescription under Schedule 4.

The Clinical Forensic Medicine Department of the Victorian Institute of Forensic Medicine is uniquely positioned to attest to the devastating consequences of benzodiazepine abuse.

- We conduct 'Fitness for Interview' examinations of detainees to determine if they can be interrogated by police. Our combined experience is that individuals detained by police are very commonly drug affected. Self-reporting by the detainees indicates a high rate of prescribed and non-prescribed benzodiazepine use.
- We provide reports to the Victoria Police Traffic Departments dealing with the effects of drugs and alcohol on driving safety and the role of these drugs in crash causation and cases of culpable driving. In many cases, the drugs causing driving impairment are benzodiazepines.
- Certificates as to drug Effect are provided by us to police under Section 57 of the *Victorian Road Safety Act*. In these cases our Authorised experts compare impairment assessments of drivers with the toxicological analyses of their blood.

In many cases, the drugs found to be causing impairment are benzodiazepines alone or in combination with other psychoactive drugs.

- The Coroner and the Australian Health Practitioners Regulation Agency refer cases for opinions on the prescribing practices of doctors. In most of these cases, the doctors have been shown to prescribe both benzodiazepines and opiates inappropriately.
- All forensic examinations of complainants of sexual assault in Victoria are conducted by examiners from the Victorian Institute of Forensic Medicine. Sexual assaults are infrequently found to be facilitated by consumption of sedative agents such as benzodiazepines. A significant percentage of all cases reported are associated with heavy alcohol use by the complainant increasing the risk of morbidity in the presence of benzodiazepine use.

Research

This submission does not include a literature review of the addictive nature of all benzodiazepines. There is authority for and acceptance of this attribute of the class of drugs.

Literature suggests that benzodiazepines may have a negative influence on many facets of human behaviour resulting in risk to themselves and others as follows:

Deaths

The Victorian Coroners Prevention Unit has collected data on deaths due to drugs and has found benzodiazepines feature in 50.3% of drug related deaths. This is exceeded only by opioid analgesics at 51.4%.¹

Driving

It is accepted that benzodiazepines cause driving impairment.² Specifically, diazepam has been found to affect attentional shifting in the temporal domain and impair dual-task performance at a therapeutic dosage.³ Alprazolam has been found to cause significant driving impairment specifically noted in the ability to maintain a lateral position and to maintain a specific speed.⁴ The effect of tolerance in the reduction of driving impairment is the subject of much discussion. Tolerance to benzodiazepine

¹ Jeremy Dwyer 'Coronial Insights into understanding and preventing drug-related harms' *Pharmaceutical Society of Australia, Harm Minimisation Forum*, 12 September 2012.

² Dassanayake T, Mitchie P, Carter G, Jones A 'Effects of benzodiazepines, antidepressants and opioids on driving: a systematic review and meta-analysis of epidemiological and experimental evidence' *Drug Safety* 2011 34(2) 125

³ Boucart M, Waucquier N, Michael G, Libersa C, 'Diazepam impairs temporal dynamics of visual attention' *Experimental Clinical Psychopharmacology* 2007 15(1) 115.

⁴ Verster J, Volkerts E, Verbaten M 'Effects of alprazolam on driving ability, memory functioning and psychomotor performance: a randomised, placebo controlled study' *Neuropsychopharmacology* 2002 27(2) 260

related impairment probably does occur but less so than for opioid medication. The prolonged use of benzodiazepines however has the potential to cause ongoing cognitive impairment.⁵

The evidence of driving impairment caused by benzodiazepines has been so recognised that legislative driving impairment limits of the drugs in whole blood has been proposed in Norway. For instance the limit suggested for alprazolam is 0.003mg/L⁶. This is a level lower than that found at therapeutic concentrations.⁷ Similar comparison can be made between the level of diazepam considered to be associated with driving impairment (0.057mg/L)⁸ compared to therapeutic levels.⁹

An audit of overdose presentations was done in an inner Melbourne emergency department. It was found that alprazolam and diazepam were over-represented in the data relative to the rate of prescriptions in the population. In this study the most common source of the medication was prescription by the patients' usual doctor.¹⁰

Association with crime

Other than well documented risk of driving impairment and the consequent risk to the public, the association of benzodiazepine use may have an association with other types of criminal behaviour.

A typical instance of the misuse of prescribed medication is that a person is arrested by police and is found to be in possession of prescribed benzodiazepines. The date of prescription commonly predates the person's arrest by a day or several days yet there are very few tablets of the prescription left. This suggests either significant overuse of the drug or diversion.

The examinations of detainees by doctors at the Victorian Institute of Forensic Medicine show a high proportion of self-reported benzodiazepine use.¹¹ It cannot however be inferred that this association is cause and effect but, as with studies which showed the presence of benzodiazepines in the blood of drivers who had crashed, the association may be more than coincidental. In a study of detainees in a remand prison the combination of alcohol and unusually high doses of benzodiazepines was shown to be

⁵ Lucki, Rickels, Geller A 'Chronic use of benzodiazepines and psychomotor and cognitive test performance' *Psychopharmacology* 1986 88 426.

⁶ Vindenes V, Jordbru D, Knapskog A et al 'Impairment based legislative limits for driving under the influence on non-alcohol drugs in Norway' *Forensic Science International* 2012 219 1-11 3.

⁷ Olaf Drummer *The Forensic Pharmacology of Drugs of Abuse* 2001 p 383

⁸ Vindenes V, Jordbru D, Knapskog A et al 'Impairment based legislative limits for driving under the influence on non-alcohol drugs in Norway' *Forensic Science International* 2012 219 1-11 3.

⁹ Olaf Drummer *The Forensic Pharmacology of Drugs of Abuse* 2001

¹⁰ Buykx P, Loxley W, Dietze P, Ritter A 'Medications used in overdose and how they are acquired - an investigation of cases attending an inner Melbourne emergency department *Australia and New Zealand Journal of Public Health* 2010 34(4) 401

¹¹ Data collected from examinations of detainees in police stations prior to interview in the year 2009 (pre-publication)

risk factors for violent crime.¹² The association between benzodiazepines and aggression has been claimed to be a rare severe reaction but it is recognised that the research into this area is limited.¹³ The risk factors noted for aggression related to benzodiazepine use are noted to be alcohol use and underlying psychopathology.¹⁴

There is evidence from coronial studies previously cited and self-reporting by detainees of their use of benzodiazepines¹⁵ that the preconditions for possible violent behaviour are met in the groups studied.

Alprazolam

Alprazolam is a benzodiazepine which has been associated with widespread illicit use. In particular alprazolam has been shown to be over-represented in benzodiazepine adverse events in Australia.¹⁶ In cases of deliberate overdose by one form of benzodiazepine, alprazolam was found to be relatively more toxic than other benzodiazepines.¹⁷ Its widespread use and misuse deserves special mention.

Data collected by the Victorian Institute of Forensic Medicine at the time of the examination of individuals arrested by police for the year 2009 indicate the self-reporting of the use of alprazolam in 26% of persons arrested on suspicion of assault. In a large number of cases there was self-reporting of the use of illicit and prescribed diazepam and other benzodiazepines. A frequent allegation against a detainee is that he or she has damaged property. The self-reporting of the use of both licit and illicit alprazolam occurred in 16% of those arrested for property damage.¹⁸

In a national Australian study, the use of alprazolam was found to be high with illicit use far exceeding licit. 83% of the national sample reported using any benzodiazepine in their lifetime.¹⁹ The same study associated the use of recent illicit alprazolam use with crime at odds ratio (OR) of 2.45 and the association with having been arrested in the past year at OR 2.26.

The use of the drug for panic disorder is now discouraged because of adverse effects such as inter-dose anxiety due to withdrawal – often mistaken by the patient for a

¹² Lundholm L, Haggard U, Moller J, et al 'The triggering effect of alcohol and illicit drugs on violent crime in a remand prison population: A case crossover study' *Drug and Alcohol Dependence* 2012 epub ahead of print.

¹³ Jones A, Nielsen S Bruno R et al 'Benzodiazepines, their role in aggression and why GPs should prescribe with caution.' *Australian Family Physician* 2011 40(11) 862.

¹⁴ Jones A, Nielsen S Bruno R et al 'Benzodiazepines, their role in aggression and why GPs should prescribe with caution.' *Australian Family Physician* 2011 40(11) 864.

¹⁵ Data from examination files at the Victorian Institute of Forensic medicine.

¹⁶ Moylan S, Glorlando F, Nordjaern T, Berk M 'The role of alprazolam for the treatment of panic disorder in Australia' *Australian and New Zealand Journal of Psychiatry* (2012) 46(3) 212-224.

¹⁷ Isbister G, O'Regan L, Sibbritt D, Whyte I 'Alprazolam is relatively more toxic than other benzodiazepines in overdose' *British Journal of Clinical Pharmacology* 2004 58(1) 88-95.

¹⁸ Data collected from examinations of detainees in police stations prior to interview in the year 2009 (pre-publication)

¹⁹ Stafford J, Burns L 'Findings from the illicit Drug Reporting System (IDRS) *Australian Drug Trends Series No. 73: National Drug and Alcohol Research Centre, University of New South Wales* (2012)

recurrence of symptoms – and its misuse. It is not considered to confer any advantage over other benzodiazepines in the treatment of panic disorder.²⁰

Sexual assault

Currently benzodiazepines have not been found to be of particular concern in cases of possible drug-facilitated sexual assault. The use of benzodiazepines by complainants of sexual assault is not known because of under-reporting and delayed reporting of these assaultive events. Hurley, Parker and Wells studied the results of toxicological analysis of complainants who may have been sexually assaulted and were examined by doctors at the Victorian Institute of Forensic Medicine. Of 76 cases examined, 49% reported using prescription medications including benzodiazepines. In the group where covert administration was suspected (15 cases) benzodiazepines were found in 4 cases.²¹

Conclusion

It is acknowledged that the Clinical Forensic Medicine Department has extensive experience with benzodiazepines and other drug abuse at levels which cause death and morbidity and an association with criminal activity. However, alternative conclusions may be reached;

- a) that this level of abuse is not reflective of the role of benzodiazepines in the community by which it follows that long term treatment with them has legitimate role,
- b) that the cohort represents only the tip of the iceberg or
- c) that the problem is pervasive.

The combined experience of the signatories to this submission leads to the last of these views and concludes that the use of benzodiazepines other than for short courses of treatment of infrequent specific indications is ill advised. It recognises that abuse of benzodiazepines is facilitated by easy availability and looks to a systemic approach in monitoring and restricting access to these drugs.

With respect to the specific harms created by the misuse of alprazolam and supported by current research, we are of the opinion that the drug should not be available for use.

The awareness of the harms and forensic implications of the misuse of benzodiazepines is not unique to the experience of this group in Victoria. Contact with colleagues interstate and through national communication via the Australian Association of

²⁰ Moylan S, Giorlando F, Nordfaern T, Berk M 'The role of alprazolam for the treatment of panic disorder in Australia' *Australian and New Zealand Journal of Psychiatry* (2012) 46(3) 212-220.

²¹ Hurley M, Parker H, Wells D 'The Epidemiology of drug facilitated sexual assault' *Journal of Clinical Forensic Medicine* (2006) 13(4) 181-185.

[REDACTED]

Forensic Physicians (AAFP) suggests that the problems are endemic. Invitation for specific comment from the members of the AAFP would be of value in assessment of the utility of decreasing the availability of this class of drugs.

[REDACTED]

[REDACTED]



Coroners Court of Victoria

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16 January 2013

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

RE: Proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8

I write in response to your notice inviting public submissions regarding a proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard).

Victoria's coroners do not ordinarily engage in public submissions processes, as our findings into individual deaths are the primary vehicle through which we highlight public health issues and make recommendations aimed at preventing further deaths. However given the potential for the rescheduling proposal to reduce significantly drug related harms and deaths in the State of Victoria, I have determined it is appropriate for me to respond to your invitation.

Please find my submission and supporting material enclosed with this covering letter. The submission represents my views as the State Coroner of Victoria, but not necessarily the views of Victoria's other coroners.

The essence of my submission is that all benzodiazepines currently classified within Schedule 4 of the Poisons Standard should be reclassified to Schedule 8 of the Poisons Standard. Benzodiazepines are among the most frequent contributing drugs in Victorian deaths involving acute drug toxicity; rescheduling them will create opportunities to prevent the inappropriate prescribing, abuse and illicit diversion that underpin so many of these deaths.

I will be pleased to consider any requests from you for further information or clarification regarding my submission. I can be contacted via my Associate [REDACTED]

Yours sincerely

Submission

Preliminary matters

Structure of the submission

Under subsection 52D(2) of the *Therapeutic Goods Act 1989* (Cwth) ('the Act'), the Secretary of the Department of Health and Ageing may amend the current Poisons Standard. In exercising this power, the Secretary must take the following matters into account where relevant under subsection 52E(2) of the Act:

- (a) the risks and benefits of the use of a substance;
- (b) the purposes for which a substance is to be used and the extent of use of a substance;
- (c) the toxicity of a substance;
- (d) the dosage, formulation, labelling, packaging and presentation of a substance;
- (e) the potential for abuse of a substance;
- (f) any other matters that the Secretary considers necessary to protect public health.

Consistent with this framework, I have structured my submission in six parts, each of which addresses one of the subsection 52E(2) matters the Secretary must take into account when considering the proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8 of the Poisons Standard.

Scope of the submission

In this submission I address the rescheduling proposal from a Victorian perspective, and do not consider the implications of the proposal for other states and territories of Australia.

Terminology

For convenience, throughout my submission I refer to the need to reschedule all benzodiazepines from Schedule 4 to Schedule 8 of the Poisons Standard. I am aware that flunitrazepam has already been moved to Schedule 8. In addition, while I refer to all benzodiazepines, my primary concern is with diazepam, alprazolam, oxazepam, temazepam and nitrazepam, which are the benzodiazepines most frequently involved in Victorian deaths.

1. Risks and benefits of benzodiazepines

I accept that benzodiazepines have therapeutic benefits for certain patients when prescribed and used appropriately. However I am deeply concerned that in Victoria benzodiazepines contribute to a substantial number of deaths from acute drug toxicity; many of these deaths occur outside the context of appropriate use and feature benzodiazepine dependence, diversion, prescription shopping,¹ inappropriate prescribing and multiple substance use.

1 I have adopted the definition of prescription shopping set out in Parliament of Victoria Drugs and Crime Prevention Committee, *Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria: Final Report*, December 2007, p.108. The definition is: "[Prescription shopping] involves patients attending several doctors in order to obtain several prescriptions for controlled drugs so as to get a quantity of drugs greater than their therapeutic needs, which are then used for personal consumption or sold on the street market".

In this section I set out the empirical evidence regarding benzodiazepine involvement in Victorian deaths from acute drug toxicity. I then discuss the recurring themes that underpin these deaths. Finally, I present my reasons why the risks that benzodiazepines present can be better managed through shifting them from Schedule 4 to Schedule 8.

1.1 Benzodiazepine contribution to Victorian deaths from acute drug toxicity

In preparing this submission I directed the Coroners Prevention Unit (CPU)² to compile relevant information on the role of benzodiazepines in Victorian deaths from acute drug toxicity; the CPU provided two reports that I have attached to this submission.

By way of introduction, I note that the information the CPU provided pertains only to Victorian deaths from acute drug toxicity in which the expert death investigator (the investigating coroner and/or forensic pathologist) determined that the acute toxic effects of one or more benzodiazepines played a causal or contributory role. This is a very conservative measure of benzodiazepine contribution to Victorian deaths, as it excludes deaths associated with chronic use and deaths where the behavioural effects of benzodiazepines may have contributed.³

The first CPU report (see Attachment A) comprised an overview of deaths from acute drug toxicity reported to the Coroners Court of Victoria in 2010 and 2011, focusing particularly on the contribution of benzodiazepines to these deaths. Pertinent findings included:

- In 2010, 338 deaths from acute drug toxicity were investigated by the Coroners Court of Victoria. Benzodiazepines were the most frequent contributing drug group in these deaths (n = 165, 48.8%), followed by illegal drugs (n = 149, 44.1%) and opioid analgesics (n = 140, 41.4%).
- In 2011, 356 deaths from acute drug toxicity were investigated by the Coroners Court of Victoria. Benzodiazepines were the second most frequent contributing drug group in these deaths (n = 179, 50.3%), closely following opioid analgesics (n = 183, 51.4%).
- In both 2010 and 2011, the benzodiazepine diazepam was the second most frequent individual contributing drug after heroin to the Victorian deaths from acute drug toxicity (for diazepam n = 108 in 2010; n = 123 in 2011; for heroin n = 139 in 2010, n = 129 in 2011).
- Among the 344 deaths (165 in 2010, 179 in 2011) from acute drug toxicity where benzodiazepines contributed, the most frequent contributing benzodiazepines were diazepam (n = 231), alprazolam (n = 99), temazepam (n = 69) and oxazepam (n = 63). The overwhelming majority of the deaths (n = 335, 97.4%) involved other drugs co-contributing with benzodiazepines. The most frequent co-contributing drugs were the illegal drug heroin (n = 134), the opioid analgesics codeine (n = 99), methadone (n = 83) and oxycodone (n = 56), the antipsychotic quetiapine (n = 53), and alcohol (n = 86).

The CPU data shows that benzodiazepines play a central role in Victorian deaths from acute drug toxicity. Expert death investigators (coroners and forensic

2 The Coroners Prevention Unit is a specialist service for Victoria's coroners created to strengthen their prevention role and provide them with assistance on issues pertaining to public health and safety.

3 Examples of the latter category would be a motor vehicle crashes where the driver's performance was affected by benzodiazepines, and a drowning where the deceased was sedated by benzodiazepines.

pathologists) found that one or more benzodiazepines contributed in approximately 50% of Victorian acute drug toxicity deaths in 2010 and 2011: a greater proportion than either opioid analgesics or illegal drugs.

The CPU data further shows that while acute benzodiazepine toxicity alone is rarely the cause of deaths, benzodiazepines are ubiquitous in deaths from multiple drug toxicity. Fatal outcomes are particularly associated with combinations of benzodiazepines and heroin, opioid analgesics, alcohol and/or antidepressants. This finding is consistent with the extensive literature demonstrating that benzodiazepines produce strong additive or synergistic depressive effects on the central nervous system when combined with a broad range of other central nervous system depressants.⁴

The high risk of fatally toxic outcomes when benzodiazepines are combined with other central nervous system depressants is clearly illustrated in the second CPU report (see Attachment B), which describes the co-contributory role benzodiazepines played in Victorian deaths from acute drug toxicity involving the Schedule 8 opioid analgesics methadone and oxycodone. Pertinent findings included:

- Among 462 deaths from acute drug toxicity including methadone that were investigated by the Coroners Court of Victoria between 1 January 2000 and 31 December 2011, 389 (84.2%) were multiple drug deaths. Benzodiazepines were the most frequent co-contributing drugs with methadone; they played a co-contributory role in 278 (71.5%) of the 389 multiple drug deaths. Diazepam was the largest individual co-contributing drug, playing a role in 228 (58.6%) of the 389 multiple drug deaths.
- Among 265 deaths from acute drug toxicity including oxycodone that were investigated by the Coroners Court of Victoria between 1 January 2000 and 31 December 2011, 233 (87.9%) were multiple drug deaths. Benzodiazepines were the most frequent co-contributing drugs with oxycodone; they played a co-contributory role in 175 (75.1%) of the 233 multiple drug deaths. Diazepam was the largest individual co-contributing drug, playing a role in 128 (54.96%) of the 233 multiple drug deaths.

Again, these findings are consistent with the well-documented depressive effects produced by the combination of benzodiazepines and opioids. They are also consistent with the literature on benzodiazepine misuse, which shows that many people misuse benzodiazepines to enhance the effects of opioids, usually for recreational and/or quasi-therapeutic purposes.⁵

4 See for example El-Guebaly N, Sareen J, Stein MB, "Are there guidelines for the responsible prescription of benzodiazepines?", *Canadian Journal of Psychiatry*, vol 55, no 11, November 2010, p.709; Charlson F, Degenhardt L, McLaren J, Hall W, Lynskey M, "A systematic review of research examining benzodiazepine-related mortality", *Pharmacoepidemiology and Drug Safety*, vol 18, no 2, February 2009, p.94; Ashton H, "Toxicity and adverse consequences of benzodiazepine use", *Psychiatric Annals*, vol 25, no 3, March 1995, p.158.

5 See for example Rowlett JK, Duke AN, Platt DM, "Abuse and dependence liability of GABA-A receptor modulators", in *The Receptors: The GABA Receptors*, edited by Enna SJ and Möhler H, 3rd edition, Totowa, New Jersey: Humana Press, 2007, pp.152-153; Griffiths RR, Weerts EM, "Benzodiazepine self-administration in humans and laboratory animals: implications for problems of long-term use and abuse", *Psychopharmacology*, vol 134, no 1, 1997, p.2; Reed K, Bond A, Witton J, Cornish R, Hickman M, Strang J, "The changing use of prescribed benzodiazepines and z-drugs and of over-the-counter codeine-containing products in England", *The National Addiction Centre*, Kings College London, 2011, p.15; Trafton JA, Ramani A, "Methadone: a new old drug with promises and pitfalls", *Current Pain and Headache Reports*, vol 13, no 1, February 2009, p.28.

1.2 Recurring themes in the deaths

The CPU reports included in Attachments A and B provide a valuable overview of benzodiazepine involvement in Victorian deaths from acute drug toxicity, however they do not provide detailed insight into the context and circumstances of the deaths, including the types of risky behaviours associated with benzodiazepine use and misuse that contributed to the deaths.

Therefore I asked CPU members who assist Victoria's coroners with investigations into a range of drug-related deaths for their observations on recurring themes in the deaths from acute drug toxicity including benzodiazepines. The following were the major themes identified:

- Many deceased obtained benzodiazepines through prescription shopping - that is, from multiple prescribers who were not aware of one another.
- Whereas prescribers usually exercised great caution with respect to Schedule 8 opioids, they often did not exercise the same caution with benzodiazepines. In a significant number of deaths, multiple doctors supplied benzodiazepines to the deceased upon request and without question.
- In many cases, the deceased had been prescribed benzodiazepines continually for several months if not years leading up to the death. On occasion the original purpose of the benzodiazepine prescribing had been entirely forgotten.
- Deaths from multiple drug toxicity including both benzodiazepines and opioids (illegal and/or prescription) occurred frequently among people with an established history of substance abuse. Of the 334 Victorian deaths from acute drug toxicity in 2010 and 2011 where benzodiazepines contributed, 139 deceased (41.6%) had an established history of substance abuse and died from the combined toxic effects of benzodiazepines and opioids.

These themes are reflected in recent findings published on the Coroners Court of Victoria website,⁶ such as Coroner John Olle's finding in the death of James (surname redacted, court reference 20095181), Coroner Audrey Jamieson's finding in the death of David Trengrove (court reference 20084042), and Deputy State Coroner Iain West's finding in the death of Rory Denman (court reference 20104232).

1.3 Managing benzodiazepine risks through rescheduling

In 2010 and 2011, benzodiazepines contributed to more Victorian deaths from acute drug toxicity than any other drug group including opioid analgesics and illegal drugs. In nearly all cases benzodiazepines combined with other drugs, particularly central nervous system depressants, to produce the fatally toxic outcome.

The prevalence of benzodiazepine contribution in Victorian deaths from acute drug toxicity strongly indicates that they are inappropriately classified as Schedule 4 poisons, which are:

Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.

Rather, they more closely fit the Schedule 8 description:

Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

⁶ Go to <<http://www.coronerscourt.vic.gov.au/home/case+findings/>>, where the public can search for findings by deceased name and/or court reference number.

Benzodiazepines

Rescheduling benzodiazepines from Schedule 4 to Schedule 8 of the Poisons Standard will create new opportunities to prevent Victorian deaths from acute drug toxicity, thus ensuring that the public can receive the therapeutic benefits of these drugs while managing associated risks.

A central prevention opportunity created by rescheduling is that benzodiazepine prescribing would need to meet the Victorian Department of Health's permit requirements for prescribing of Schedule 8 poisons, which include:

In order to ensure that Schedule 8 poisons are available to patients with genuine therapeutic needs whilst minimising the potential for concurrent prescribing and successful drug-seeking activities, medical practitioners must obtain a permit (section 34A(1)) from DPRG [the Drugs and Poisons Regulation Group]:

- Before treating a drug-dependent person with any Schedule 8 poison. Permits to prescribe pharmacotherapy to treat opioid-dependence may be issued to medical practitioners who have been specifically approved by the DPRG.
- To treat a person, who is not drug-dependent, with any Schedule 8 poison for a period greater than 8 weeks [...].⁷

With the permit requirements in place, prospective benzodiazepine prescribers would be required to reflect on the appropriateness of long-term prescribing and the dangers of prescribing to drug-dependent persons. In addition the Department of Health would be alerted when a doctor intended to prescribe to a person who was already receiving benzodiazepines and/or Schedule 8 opioids, and would be able to intervene with alerts and safety information. Prescription shopping for benzodiazepines would become much more difficult, thus reducing misuse and diversion of the drugs and associated deaths.

Further to this last point, another important prevention opportunity that would be facilitated through rescheduling benzodiazepines to Schedule 8 of the Poisons Standard, pertains to the real-time prescription monitoring system that is being developed and implemented throughout Australia to prevent prescription shopping and associated harms and deaths associated with prescription drug diversion and misuse.

The Australian Government has committed to introducing a real-time prescription monitoring system called the Electronic Recording and Reporting of Controlled Drugs initiative, or ERRCD. The ERRCD will collect information on all dispensing of Controlled Drugs (defined as Schedule 8 poisons), and make this data available to prescribers and dispensers:

During a clinical interaction, authorised prescribers and pharmacists may access data on a consumer via a secure web portal that may help to inform their clinical decision-making. The ability of prescribers and pharmacists to view the history of Controlled Drugs that have been dispensed to a consumer will be a key feature of the system.⁸

If benzodiazepines are rescheduled to Schedule 8 of the Poisons Standard, all prescribing and dispensing will be recorded under the ERRCD initiative and the

7 Victorian Department of Health, "Schedule 8 permit requirements plus notification requirements: information for medical practitioners", September 2010.

8 Australian Government Department of Health and Ageing, "Electronic Recording and Reporting of Controlled Drugs: Fifth Community Pharmacy Agreement Other Initiatives Factsheet", April 2012.

information made available to all prescribers and dispensers. This will further curtail opportunities for prescription shopping. Prescribers will know when a patient is receiving central nervous system depressants - particularly Schedule 8 opioids such as methadone and oxycodone - so they will be able to assess the appropriateness of the benzodiazepine prescribing put in place safety measures if necessary. The overall result, it is hoped, would be a reduction in harms and particularly deaths caused by multiple drug toxicity including benzodiazepines.

A third benefit is that the restrictions and requirements for prescribing Schedule 8 poisons in Victoria, closely match current clinical guidelines for prescribing benzodiazepines.

At present the benzodiazepines that contribute most frequently to Victorian deaths from acute drug toxicity are diazepam, alprazolam, oxazepam, temazepam and nitrazepam. The main approved clinical indications⁹ for these benzodiazepines are to treat anxiety, panic disorder, insomnia and (for diazepam) symptoms of alcohol withdrawal.

I note that a broad range of recent clinical guidelines published both in Australia and internationally emphasise that, except in certain circumstances, benzodiazepines should only be prescribed on a short-term basis to treat the above conditions. For example:

- Recent guidelines for treatment of generalised anxiety disorder indicate that benzodiazepines can be used at any time to treat short-term (four to six weeks), acute, severe exacerbations of generalised anxiety disorder. In addition they are an appropriate short-term second-line treatment for generalised anxiety if first-line treatments such as psychological therapies and treatment with certain antidepressants fails.¹⁰
- Recent guidelines for treatment of panic disorder vary in their advice regarding benzodiazepines. The range of advice includes that benzodiazepines should never be prescribed for panic disorder, that benzodiazepines should only be used for short-term treatment of severe panic disorder, and that benzodiazepines can be used as a final resort when the patient cannot tolerate other recommended drugs.¹¹

9 As approved by the Therapeutic Goods Administration and listed on the Australian Register of Therapeutic Goods (ARTG). See Therapeutic Goods Administration, "eBS Australian Register of Therapeutic Goods and Devices", <<https://www.ebs.tga.gov.au/ebs/ANZTPAR/PublicWeb.nsf/cuDevices?OpenView>>, accessed 5 March 2012.

10 Therapeutic Guidelines, <<http://online.tg.org.au/ip/>>, *eTG Complete*, accessed 2 March 2012; Canadian Psychiatric Association, "Clinical Practice Guidelines: Management of Anxiety Disorders", *Canadian Journal of Psychiatry*, vol 51, supplement 2, July 2006; National Institute for Health and Clinical Excellence, "Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults: management in primary, secondary and community care," *NICE Clinical Guideline 113*, January 2011; Western Australian Psychotropic Drugs Committee, "Anxiety Disorders: Drug Treatment Guidelines", August 2008.

11 Therapeutic Guidelines, <<http://online.tg.org.au/ip/>>, *eTG Complete*, accessed 2 March 2012; Canadian Psychiatric Association, "Clinical Practice Guidelines: Management of Anxiety Disorders", *Canadian Journal of Psychiatry*, vol 51, supplement 2, July 2006; National Institute for Health and Clinical Excellence, "Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults: management in primary, secondary and community care," *NICE Clinical Guideline 113*, January 2011; Western Australian Psychotropic Drugs Committee, "Anxiety Disorders: Drug Treatment Guidelines", August 2008.

- Recent guidelines for treatment of insomnia indicate that a benzodiazepine is an appropriate treatment for acute insomnia expected to resolve within four weeks. Otherwise, a benzodiazepine might be an appropriate second-line treatment for chronic insomnia.¹²
- Recent guidelines for treatment of alcohol withdrawal symptoms identify diazepam as the gold standard first-line treatment. The recommended fixed dosing schedule for this purpose extends no longer than six days.¹³
- Throughout all the clinical guidelines, there are repeated warnings regarding the risk that patients will develop tolerance to and dependence on benzodiazepines if prescribed for a prolonged period (greater than four to six weeks).

The Victorian Department of Health requirement that a medical practitioner should obtain a permit to prescribe a Schedule 8 poison (a) for a period greater than eight weeks, or (b) to a drug-dependent person, closely aligns with the principles enunciated in the above clinical guidelines.

1.4 Concluding comment

In Chapter 3 of the *Scheduling Policy Framework for Medicines and Chemicals* dated 1 July 2010, the National Coordinating Committee on Therapeutic Goods set out its principles for poison scheduling and the standardised set of factors to be considered when making a scheduling decision. Three specific factors were listed for Schedule 8 controlled drugs:

1. The substance is included in Schedule I or II of the United Nations Single Convention on Narcotic Drugs 1961 or in Schedule II or III of the United Nations Convention on Psychotropic Substances 1971.
2. The substance has an established therapeutic value but its use, at established therapeutic dosage levels, is recognised to produce dependency and has a high propensity for misuse, abuse or illicit use.
3. The substance has an established therapeutic value but by reason of its novelty or properties carries a substantially increased risk of producing dependency, misuse, abuse or illicit use.¹⁴

I acknowledge that benzodiazepines have an established therapeutic value. However I submit that this therapeutic value must be balanced against the large number of Victorian deaths from acute drug toxicity involving benzodiazepines, and the misuse and abuse, prescription shopping and illicit diversion that underpins many of these deaths. These factors make Schedule 8 a more appropriate classification than Schedule 4 for benzodiazepines, with regard to the *Scheduling Policy Framework*.

12 National Prescribing Service, "Addressing hypnotic medicines use in primary care", *NPS Newsletter*, no 67, February 2010; British Association for Psychopharmacology, "Consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders", *Journal of Psychopharmacology*, vol 24, no 11, November 2010; American Academy of Sleep Medicine, "Clinical Guideline for the Evaluation and Management of Chronic Insomnia in Adults", *Journal of Clinical Sleep Medicine*, vol 4, no 5, 15 October 2008; Therapeutic Guidelines, <<http://online.tg.org.au/ip/>>, *eTG Complete*, accessed 2 March 2012.

13 Haber P, Lintzeris N, Proude E, Lopatko O, *Guidelines for the Treatment of Alcohol Problems*, Australian Government Department of Health and Ageing, June 2009; Amato L, Minozzi S, Vecchi S, Davoli M, "Benzodiazepines for alcohol withdrawal (Review)", *The Cochrane Library*, issue 3, 2010.

14 National Coordinating Committee on Therapeutic Goods, *Scheduling Policy Framework for Medicines and Chemicals*, 1 July 2010, p.25.

2. The purpose and extent of benzodiazepine use

I do not make any submission regarding the purpose and extent of benzodiazepine use.

3. The toxicity of benzodiazepines

The data provided by the CPU clearly demonstrates that although benzodiazepines alone are rarely the cause of Victorian deaths from acute drug toxicity, they frequently contribute to deaths in combination with other drugs, particularly central nervous system depressants such as heroin, pharmaceutical opioids, alcohol, antidepressants and certain antipsychotics. In assessing the toxicity of benzodiazepines, it is essential to consider the ubiquity of benzodiazepines in deaths from combined drug toxicity.

4. Dosage, formulation, labelling, packaging and presentation

I do not make any submission regarding the dosage, formulation, labelling, packaging and/or presentation of benzodiazepines.

5. The potential for benzodiazepine abuse

There is an extensive literature on benzodiazepine abuse and associated phenomena such as the reinforcing effect of benzodiazepines and the development of tolerance, dependence and withdrawal symptoms among users.¹⁵ As already discussed, substance abuse - including abuse of benzodiazepines - features frequently among Victorian deaths from acute drug toxicity.

6. Any other matters

My colleague Coroner Audrey Jamieson made the following recommendation to the Commonwealth Department of Health and Ageing in her finding dated 18 May 2012 for the death of David Trengrove (court reference 20084042):

Recommendation 3. To reduce the harms and death associated with benzodiazepine use in Victoria, within 12 months the Therapeutic Goods Administration of the Australian Government Department of Health and Ageing should move all benzodiazepines into Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons.

In the Therapeutic Goods Administration response to this recommendation dated 6 November 2012, National Manager Dr John Skerrett listed 11 factors that he considered in evaluating Coroner Jamieson's recommendation. These factors are reproduced verbatim here:

- The finding that Mr Trengrove died from the toxic effects of morphine in a setting of benzodiazepine dependency.

¹⁵ See for example Tan KR, Rudolph U, Luscher C, "Hooked on benzodiazepines: GABA-A receptor subtypes and addiction", *Trends in Neurosciences*, vol 34, no 4, April 2011; Lalive AL, Rudolph U, Luscher C, Tan KR, "Is there a way to curb benzodiazepine addiction?", *Swiss Medical Weekly*, vol 141, 19 October 2011; Sievwright NA, Dougal W, "Benzodiazepine misuse", *Current Opinion in Psychiatry*, vol 5, no 3, June 1992; Charlson F, Degenhardt L, McLaren J, Hall W, Lynskey M, "A systematic review of research examining benzodiazepine-related mortality", *Pharmacoepidemiology and Drug Safety*, vol 18, no 2, February 2009; Rowlett JK, Duke AN, Platt DM, "Abuse and dependence liability of GABA-A receptor modulators", in *The Receptors: The GABA Receptors*, edited by Enna SJ and Möhler H, 3rd edition, Totowa, New Jersey: Humana Press, 2007; Licata SC, Rowlett JK, "Abuse and dependence liability of benzodiazepine-type drugs: GABA-A receptor modulation and beyond", *Pharmacology Biochemistry and Behavior*, vol 90, no 1, July 2008.

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- The uncertainty about the role that benzodiazepines played in Mr Trengrove's death.
- Mr Trengrove's medical history (including his "significant history of mental ill health including schizophrenia, depression and psychosis" and his "history of use of ecstasy, protein supplements, alcohol and injecting testosterone and other steroids").
- The multiple medications he was using at the time of his death.
- The prescribing and use of prescription-only benzodiazepines in a manner contrary to the medicine's published Product Information, including Mr Trengrove's abuse of these prescription medications.
- Mr Trengrove's practice of "Doctor / Prescription Shopping".
- The admissions of Dr Thai Chin Lim "that his prescribing of benzodiazepines to Mr Trengrove was excessive and not correct".
- The lack of evidence that inclusion of benzodiazepines in Schedule 8 would have prevented Mr Trengrove's death, noting that general practitioners are still able to prescribe Schedule 8 medicines (albeit under a stricter regulatory framework).
- The further cost to Australian taxpayers of governments regulating benzodiazepines as Schedule 8 medicines.
- The additional regulatory impact upon the pharmaceutical industry of regulating benzodiazepines as Schedule 8 medicines.
- That benzodiazepines continue to be supplied as prescription-only medicines in countries such as the United Kingdom and USA.

Dr Skerrett concluded that, having considered these factors:

[...] on balance, the TGA does not agree with the coroner's recommendation that all benzodiazepines should be moved into Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons.

I note that this public consultation process was announced only three weeks after the TGA rejected Coroner Jamieson's recommendation. It is my respectful submission that the Therapeutic Goods Administration use the public consultation process as an opportunity to reconsider its position, as benzodiazepines contribute to a large number of Victorian deaths every year and moving them to Schedule 8 will create new opportunities to prevent these deaths.

Attachment A

Victorian deaths from acute drug toxicity, 2010-2011

The Coroners Prevention Unit (CPU) maintains a database of deaths from acute drug toxicity investigated by the Coroners Court of Victoria. The CPU used this database to prepare Attachment A, which describes deaths from acute drug toxicity reported to the Court in the years 2010 and 2011, and focuses on the contribution of benzodiazepines to these deaths.

A1. Acute drug deaths database

The following is a basic description of the CPU's acute drug deaths database, and the cases and data it contains.

A1.1 Definitions

Where a death is currently under investigation by a coroner, it is described as an 'open case'; likewise, where a coroner has completed his or her investigation into a death it is described as a 'closed case'.

The CPU definition of the term 'drug' is largely consistent with the Australian Bureau of Statistics (ABS) definition, encompassing substances that "may be used for medicinal or therapeutic purposes, or to produce a psychoactive effect".¹⁶ Like the ABS, the CPU excludes tobacco and volatile solvents such as petrol and toluene from its definition of a drug. However, the CPU considers alcohol to be a drug, whereas it is excluded under the ABS definition.

A death from acute drug toxicity is a death for which the acute toxic effects of one or more drugs played a causal or contributory role. More specifically, a death from single drug toxicity is a death for which the acute toxic effect of a single drug contributed; a death from multiple drug toxicity is a death for which the acute toxic effects of two or more drugs contributed.

A1.2 Inclusion criteria

To be coded as a death from acute drug toxicity, the death must meet one of the following two criteria:

- the coroner's death investigation was complete and the coroner found that acute drug toxicity played a causal or contributory role in the death; or
- the coroner's death investigation was still under way and the forensic pathologist determined that acute drug toxicity played a causal or contributory role in the medical cause of death.

Deaths from causes other than acute drug toxicity where consumption of drugs by the deceased or another person may have contributed to the death (such as motor vehicle crashes and drownings) are excluded.

A1.3 Case identification

The CPU identifies potentially relevant deaths through searches (including keyword searches and coded field searches) of the CPU surveillance database, the National Coroners Information System (NCIS), and other coronial data repositories. The CPU uploads all potentially relevant deaths into the acute drug deaths database and reviews them to determine whether they meet the inclusion criteria.

16. Australian Bureau of Statistics, "Drug-induced deaths: a guide to ABS causes of death data", 8 August 2002, p.2.

A1.4 Data collection

For each death meeting the inclusion criteria, the CPU records the following information: the deceased's age and sex; cause of death; and the suburb and local government area where the fatal drug consumption occurred. Additionally the CPU records every drug that the expert death investigator (coroner for closed cases, forensic pathologist for open cases) found to have made an acute toxic contribution to the cause of death. The coding rules for contributing drugs are:

- If the finding or forensic pathology report explicitly nominates the specific contributing drugs (for example "1(a) combined toxic effects of morphine and diazepam"), each nominated drug is coded as contributory.
- If the finding or forensic pathology report does not explicitly nominate the specific contributing drugs (for example "1(a) combined drug toxicity"), all drugs present in post-mortem toxicology are coded as contributory.

Further enhanced data is recorded where needed for specific projects; for example the deceased's history of drug use and abuse is recorded in many deaths, as is any evidence of prescription shopping behaviour.

A1.5 Limitations

The database only contains confirmed deaths from acute drug toxicity reported to the Court. Where (for example) a cause of death is not ascertained, or the contribution of acute drug toxicity is not clearly indicated, or contributing drugs cannot be established, the death is not included in the database, which may lead to an under-estimation of Victorian deaths from acute drug toxicity.

A2. Victorian deaths involving acute drug toxicity, 2010-2011

The CPU used the database to identify all deaths from acute drug toxicity that were reported to the Coroners Court of Victoria in the period 1 January 2010 to 31 December 2011.

A2.1 Annual frequency of deaths from acute drug toxicity

Table A1 shows the annual frequency of Victorian deaths from acute drug toxicity by drug involvement (single drug toxicity versus multiple drug toxicity) for 2010 and 2011. There was a slight increase between 2010 and 2011, which in the absence of broader trends data is probably not notable. Just over a third of deaths from acute drug toxicity each year involved a single drug, with the remainder involving two or more drugs.

Table A1: Annual frequency of deaths from acute drug toxicity by drug involvement, Victoria 2010-2011.

Drug involvement	2010	2011
Single drug toxicity	123 (36.4%)	129 (36.2%)
Multiple drug toxicity	215 (63.6%)	227 (63.8%)
<i>Total</i>	338 (100.0%)	356 (100.0%)

A2.2 Drug contribution by group to death

To explore further the drugs involved in these deaths, the CPU classified each drug that contributed in each death using a modified version of the Drug Abuse Warning Network (DAWN) Drug Vocabulary level two groupings. The major CPU departure from DAWN practice, was that the CPU split the DAWN 'anxiolytics, sedatives, and hypnotics' category into a 'benzodiazepines' category and a 'non-benzodiazepine anxiolytics, sedatives, and hypnotics' category, so that benzodiazepine contribution to deaths was clear.

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Table A2 shows the most frequent contributing drug groups to Victorian deaths from acute drug toxicity in 2010 and 2011.¹⁷ Benzodiazepines were the top contributing drug group in 2010 (n = 165, 48.8%), following by illegal drugs (n = 149, 44.1%) then opioid analgesics (n = 140, 41.4%). In 2011, opioid analgesics moved to be the top contributing drug group (n = 183, 51.4%), followed closely by benzodiazepines (n = 179, 50.3%) then illegal drugs (n = 153, 43.0%).

Table A2: Annual frequency of drug group contribution in deaths from acute drug toxicity, Victoria 2010-2011.

Drug group	2010 (n = 338)	2011 (n = 356)
Benzodiazepines	165 (48.8%)	179 (50.3%)
Illegal drugs	149 (44.1%)	153 (43.0%)
Opioid analgesics	140 (41.4%)	183 (51.4%)
Antidepressants	102 (30.2%)	99 (27.8%)
Alcohol	82 (24.3%)	85 (23.9%)
Antipsychotics	64 (18.9%)	64 (18.0%)

A2.3 Individual contributing drugs

Table A3 shows the most frequent contributing individual drugs in Victorian deaths from acute drug toxicity for 2010 and 2011.¹⁸ The illegal drug heroin was the most frequent individual contributor in both years, followed by the benzodiazepine diazepam. Other benzodiazepines included on the list were alprazolam, temazepam and oxazepam.

Table A3: Annual frequency of individual drug contribution in deaths from acute drug toxicity, Victoria 2010-2011.

Drug	Drug group	2010	2011
Heroin	Illegal	139 (41.1%)	129 (36.2%)
Diazepam	Benzodiazepine	108 (32.0%)	123 (34.6%)
Alcohol	Alcohol	82 (24.3%)	85 (23.9%)
Alprazolam	Benzodiazepine	56 (16.6%)	43 (12.1%)
Codeine	Opioid analgesic	55 (16.3%)	66 (18.5%)
Methadone	Opioid analgesic	53 (15.7%)	72 (20.2%)
Oxycodone	Opioid analgesic	38 (11.2%)	46 (12.9%)
Quetiapine	Antipsychotic	37 (10.9%)	33 (9.3%)
Amitriptyline	Antidepressant	25 (7.4%)	21 (5.9%)
Citalopram	Antidepressant	21 (6.2%)	21 (5.9%)
Temazepam	Benzodiazepine	21 (6.2%)	48 (13.5%)
Mirtazapine	Antidepressant	20 (5.9%)	23 (6.5%)
Paracetamol	Non-opioid analgesic	20 (5.9%)	24 (6.7%)
Oxazepam	Benzodiazepine	19 (5.6%)	44 (12.4%)
Methamphetamine	Illegal	14 (4.1%)	29 (8.1%)

17 Table A2 includes drug groups that contributed in at least 10% of Victorian deaths from acute drug toxicity in 2010 or 2011.

18 Table A3 includes individual drugs that contributed in at least 20 Victorian deaths from acute drug toxicity in 2010 or 2011.

A2.4 Deaths involving acute benzodiazepine toxicity

To determine the role of benzodiazepines in Victorian deaths from acute drug toxicity, the CPU pooled for further analysis the 344 Victorian deaths (165 in 2010, 179 in 2011) in which one or more benzodiazepines contributed.

Table A4 shows, in decreasing order of frequency, the individual benzodiazepines that contributed in each of the 344 deaths.¹⁹ The most frequent contributing benzodiazepine was diazepam ($n = 231$, 67.2%) followed by alprazolam ($n = 99$, 28.8%) then temazepam ($n = 69$, 20.1%).

Table A4: Frequency of individual benzodiazepine contribution in the 344 deaths from acute drug toxicity, Victoria 2010-2011.

Benzodiazepine	n	%
Diazepam	231	67.2%
Alprazolam	99	28.8%
Temazepam	69	20.1%
Oxazepam	63	18.3%
Nitrazepam	27	7.8%
Clonazepam	23	6.7%
Midazolam	4	1.2%
Flunitrazepam	3	0.9%
Lorazepam	3	0.9%

Table A5 shows the 334 deaths from acute drug toxicity involving benzodiazepines, tabulated by the number of contributing benzodiazepines (one versus two or more), and by the number of non-benzodiazepine drugs that contributed (none versus one or more). Nine deaths (2.6%) involved acute toxic effects of benzodiazepines alone, whereas the remaining deaths ($n = 335$, 97.4%) involved benzodiazepines in combination with other drugs.

Table A5: Frequency of deaths from acute drug toxicity including benzodiazepines, by number of contributing benzodiazepines and number of co-contributing non-benzodiazepine drugs, Victoria 2010-2011.

Number of contributing benzodiazepines	Number of other (non-benzodiazepine) co-contributing drugs		
	None	One or more	Total
One	8 (2.3%)	206 (59.9%)	214 (62.2%)
More than one	1 (0.3%)	129 (37.5%)	130 (27.8%)
Total	9 (2.6%)	335 (97.4%)	344 (100%)

Table A6 shows the most frequent co-contributing drug groups in the 334 deaths from acute drug toxicity involving benzodiazepines.²⁰ Opioid analgesics are the top co-contributors ($n = 225$, 65.4%) followed by illegal drugs ($n = 150$, 43.6%) and antidepressants ($n = 145$, 42.2%).

19 Benzodiazepines that do not appear in the table (such as bromazepam, clobazam and triazolam) did not contribute in any deaths from acute drug toxicity during the period.

20 Table A5 includes drug groups that co-contributed in at least 10% of Victorian deaths from acute drug toxicity involving benzodiazepines in 2010-2011.

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Table A6: Frequency of non-benzodiazepine drug group co-contribution to the 334 deaths from acute drug toxicity including benzodiazepines, Victoria 2010-2011.

Drug group	n	%
Opioid analgesics	225	65.4%
Illegal drugs	150	43.6%
Antidepressants	145	42.2%
Antipsychotics	98	28.5%
Alcohol	86	25.0%

Table A7 shows the individual drugs that most frequently co-contributed in the 334 deaths from acute drug toxicity involving benzodiazepines.²¹ With the exception of alcohol, the top five most frequent co-contributing individual drugs were all opioids: heroin, codeine, methadone and oxycodone.

Table A7: Frequency of individual drug contribution in deaths from acute drug toxicity, Victoria 2010-2011.

Drug	Drug group	n	%
Heroin	Illegal	134	39.0%
Codeine	Opioid analgesic	99	28.8%
Alcohol	Alcohol	86	25.0%
Methadone	Opioid analgesic	83	24.1%
Oxycodone	Opioid analgesic	56	16.3%
Quetiapine	Antipsychotic	53	15.4%
Citalopram	Antidepressant	34	9.9%
Mirtazapine	Antidepressant	32	9.3%
Amitriptyline	Antidepressant	29	8.4%
Paracetamol	Non-opioid analgesic	29	8.4%
Olanzapine	Antipsychotic	26	7.6%
Methamphetamine	Illegal	24	7.0%
Doxylamine	Antihistamine	21	6.1%
Tramadol	Opioid analgesic	21	6.1%
Venlafaxine	Antidepressant	20	5.8%

²¹ Table A6 includes individual drugs that co-contributed in at least 20 Victorian deaths from acute drug toxicity involving benzodiazepines in 2010-2011.

Attachment B

Methadone, oxycodone and benzodiazepines

The database of deaths from acute drug toxicity investigated by the Coroners Court of Victoria, was described in detail in Attachment A to this submission. The CPU used this database to prepare Attachment B, which describes the subsets of deaths from acute drug toxicity including methadone and oxycodone reported to the Court in the years 2000 to 2011, and highlights the co-contributory role of benzodiazepines in these deaths.

B1. Victorian acute drug deaths involving methadone, 2000-2011

The CPU used the database to identify all deaths from acute drug toxicity including methadone that were investigated by the Coroners Court of Victoria in the period 1 January 2000 to 31 December 2011.

B1.1 Annual frequency of deaths

The CPU identified 462 Victorian deaths from acute drug toxicity including methadone reported to the Court between 2000 and 2011.

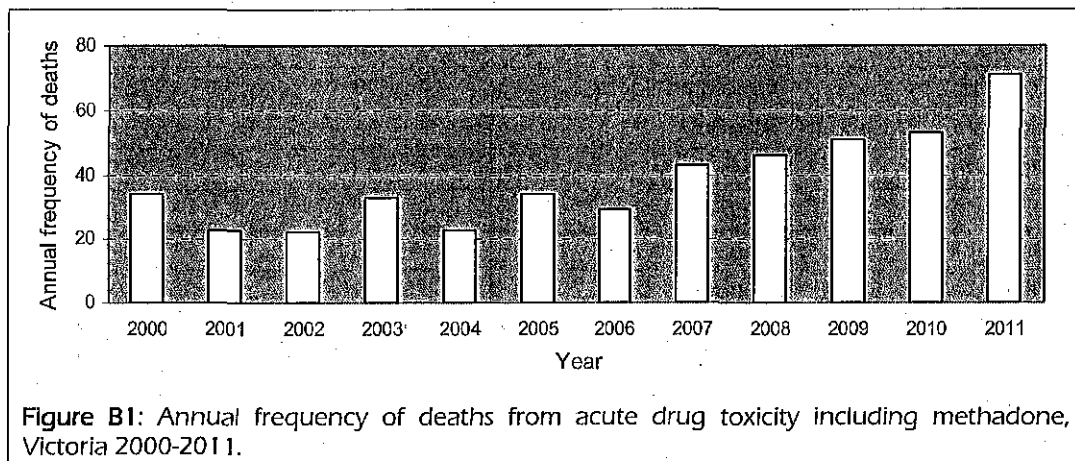


Figure B1 shows the annual frequency of deaths fluctuated between 2000 and 2005, before settling into a pattern of consistent year-on-year increases between 2006 and 2011. Notably, the annual frequency jumped from 53 deaths to 71 deaths between 2010 and 2011 - an increase of 34%.

B1.2 Co-contributing drugs

Table B1 shows the frequency of deaths from acute drug toxicity including methadone, by drug involvement (methadone alone versus methadone in combination with at least one other drug). The majority of deaths ($n = 389$, 84.2%) were from multiple drug toxicity.

Table B1: Deaths from acute drug toxicity including methadone classified by drug involvement, Victoria 2000-2011.

Drug involvement	n	%
Multiple drugs including methadone	389	84.2%
Methadone alone	73	15.8%
<i>Total</i>	<i>462</i>	<i>100%</i>

Using the same drug group classifications that were described in Attachment A, the CPU examined the drug groups that most frequently co-contributed with methadone

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in the 389 multiple drug deaths. Table B2 shows that benzodiazepines were the most frequent co-contributors; they played a role in 278 multiple drug deaths involving methadone (71.5%). The next two most frequent contributing groups were illegal drugs (n = 157, 40.4%) and antidepressants (n = 148, 38.0%).²²

Table B2: Frequency of drug group co-contribution to multiple drug deaths including methadone, Victoria 2000-2011.

Drug group	n	% of multiple drug deaths (n = 389)	% of all deaths (n = 462)
Benzodiazepines	278	71.5%	60.2%
Illegal drugs	157	40.4%	34.0%
Antidepressants	148	38.0%	32.0%
Opioid analgesics	125	32.1%	27.1%
Antipsychotics	76	19.5%	16.5%
Alcohol	68	17.5%	14.7%

Table B3 shows the most frequent individual drugs that co-contributed to the 389 deaths from multiple drug toxicity including methadone.²³

Table B3: Most frequent individual co-contributing drugs to multiple drug deaths including methadone, Victoria 2000-2011. (%M is percentage of multiple drug deaths involving methadone; %A is percentage of all deaths involving methadone).

Drug	Drug group	n	%M	%A
Diazepam	Benzodiazepine	228	58.6%	49.4%
Heroin	Illegal	122	31.4%	26.4%
Codeine	Opioid analgesic	78	20.1%	16.9%
Alcohol	Alcohol	68	17.5%	14.7%
Alprazolam	Benzodiazepine	57	14.7%	12.3%
Oxazepam	Benzodiazepine	48	12.3%	10.4%
Methamphetamine	Illegal	45	11.6%	9.7%
Temazepam	Benzodiazepine	39	10.0%	8.4%
Olanzapine	Antipsychotic	32	8.2%	6.9%
Amitriptyline	Antidepressant	29	7.5%	6.3%
Nitrazepam	Benzodiazepine	29	7.5%	6.3%
Mirtazapine	Antidepressant	28	7.2%	6.1%
Oxycodone	Opioid analgesic	24	6.2%	5.2%
Paracetamol	Non-opioid analgesic	24	6.2%	5.2%
Quetiapine	Antipsychotic	24	6.2%	5.2%
Citalopram	Antidepressant	21	5.4%	4.5%
Venlafaxine	Antidepressant	19	5.0%	4.1%

The two most frequent co-contributing drugs in deaths from multiple drug toxicity including methadone were the benzodiazepine diazepam (n = 228, 49.4% of all deaths) and the illegal drug heroin (n = 122, 26.4%). Together with diazepam, four

²² Table B2 shows the drug groups that co-contributed in at least 10% of deaths from acute drug toxicity including methadone.

²³ Table B3 shows the individual drugs that co-contributed in at least 5% of the 389 deaths from multiple drug toxicity including methadone.

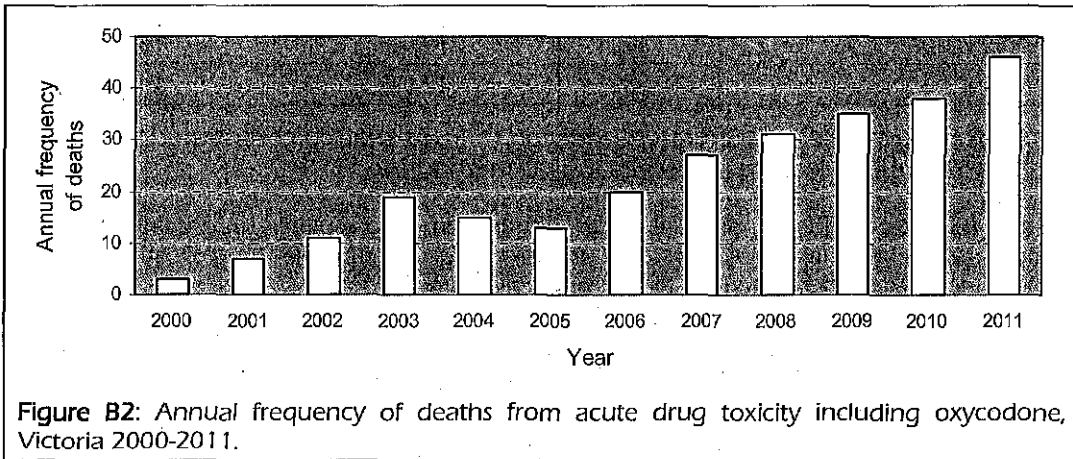
other benzodiazepines were found to be frequent contributors: alprazolam, oxazepam, temazepam and nitrazepam.

B2. Victorian acute drug deaths involving oxycodone, 2000-2011

The CPU used the database to identify all deaths from acute drug toxicity including oxycodone that were reported to the Coroners Court of Victoria in the period 1 January 2000 to 31 December 2011.

B2.1 Annual frequency of deaths

The CPU identified 265 Victorian deaths involving acute oxycodone toxicity reported to the Court between 2000 and 2011. Figure B2 shows the annual frequency of deaths for the period 2000-2011. There was a steady increase in the annual frequency over time, from three deaths in 2000 to 46 deaths in 2011.



B2.2 Co-contributing drugs

Table B4 shows the frequency of deaths from acute drug toxicity including oxycodone, by drug involvement (oxycodone alone versus oxycodone in combination with at least one other drug). The majority of deaths (n = 233, 87.9%) were from multiple drug toxicity.

Table B4: Deaths from acute drug toxicity including oxycodone, classified by drug involvement, Victoria 2000-2011.

Drug involvement	n	%
Multiple drugs including oxycodone	233	87.9%
Oxycodone alone	32	12.1%
Total	265	100.0%

Table B5 shows that the drug groups that most frequently co-contributed with oxycodone to the 233 deaths from multiple drug toxicity.²⁴ Benzodiazepines were the most frequent co-contributors (n = 175, 71.5%), followed by antidepressants (n = 118, 50.6%) and opioid analgesics (n = 114, 48.9%).

Table B6 shows the individual drugs that most frequently co-contributed to the 233 deaths from multiple drug toxicity including oxycodone.²⁵

²⁴ Table B5 shows the drug groups that co-contributed in at least 10% of deaths from acute drug toxicity including oxycodone.

²⁵ Table B6 shows the individual drugs that co-contributed in at least 5% of the 265 deaths from multiple drug toxicity including oxycodone.

Benzodiazepines

Table B5: Frequency of drug group co-contribution to multiple drug deaths involving methadone, Victoria 2000-2011.

Drug group	n	% of multiple drug deaths (n = 389)	% of all deaths (N = 462)
Benzodiazepines	175	75.1%	66.0%
Antidepressants	118	50.6%	44.5%
Opioid analgesics	114	48.9%	43.0%
Alcohol	68	29.2%	25.7%
Illegal drugs	43	18.5%	16.2%
Non-opioid analgesics	40	17.2%	15.1%
Antipsychotics	39	16.7%	14.7%
Non-benzodiazepine anxiolytics, sedatives, hypnotics	28	12.0%	10.6%

Table B6: Most frequent individual co-contributing drugs to multiple drug deaths including oxycodone, Victoria 2000-2011. (%M is percentage of multiple drug deaths involving oxycodone; %A is percentage of all deaths involving oxycodone).

Drug	Drug group	n	%M	%A
Diazepam	Benzodiazepine	128	54.9%	48.3%
Alcohol	Alcohol	68	29.2%	25.7%
Codeine	Opioid analgesic	64	27.5%	24.2%
Alprazolam	Benzodiazepine	41	17.6%	15.5%
Paracetamol	Non-opioid analgesic	36	15.5%	13.6%
Citalopram	Antidepressant	31	13.3%	11.7%
Amitriptyline	Antidepressant	30	12.9%	11.3%
Oxazepam	Benzodiazepine	30	12.9%	11.3%
Heroin	Illegal	28	12.0%	10.6%
Temazepam	Benzodiazepine	26	11.2%	9.8%
Methadone	Opioid analgesic	24	10.3%	9.1%
Tramadol	Opioid analgesic	24	10.3%	9.1%
Quetiapine	Antipsychotic	21	9.0%	7.9%
Doxylamine	Non-benzo anxiolytic	17	7.3%	6.4%
Mirtazapine	Antidepressant	17	7.3%	6.4%
Venlafaxine	Antidepressant	16	6.9%	6.0%
Fluoxetine	Antidepressant	15	6.4%	5.7%
Clonazepam	Benzodiazepine	13	5.6%	4.9%
Methamphetamine	Illegal	13	5.6%	4.9%
Morphine	Opioid analgesic	13	5.6%	4.9%

The benzodiazepine diazepam was the most frequent co-contributing drug (n = 128, 54.9%). Other frequent contributing benzodiazepines included alprazolam, oxazepam, temazepam and clonazepam.



17th January 2013

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

**Submission regarding the proposal to reschedule benzodiazepines from
Schedule 4 to Schedule 8.**

As a community pharmacy involved in the supply of pharmacy services to a wide range of clients in a variety of settings, the proposed rescheduling of benzodiazepines raises a number of areas of concern. This is most conspicuously evident in the Aged Care Homes (ACH) area of our practice.

Four main areas of concern are detailed below and all impact in some way upon one or more of the matters mentioned in section 52E of the *Therapeutic Goods Act 1989*.

1. Availability of suitable storage

Pharmacy

Our pharmacy currently utilises 3 large drug safes to provide storage of Schedule 8 medications to statutory standards. The addition of benzodiazepine to this level of secure storage would involve the purchase and installation of a bank vault style of safe to contain the hundreds of packs needed to supply our clients' current needs for these medicines, as prescribed by their doctors.

Aged Care Homes

The capacity of ACH's to store their current stocks of Schedule 8 medicines is, in most cases, close to capacity. The addition of benzodiazepines to this would necessitate a significant increase in secure storage capacity at considerable expense to the ACF's so affected.

2. Administrative demands

Pharmacy

The demands upon pharmacists and technicians to track and properly document the movement of such a large volume of Schedule 8 medicines would be onerous at best. The registers would need to be expanded several fold to accommodate the record keeping and reporting functions alone. The additional time burden on pharmacist dispensing time would need to be carefully considered in regard to their capacity to provide the professional services required in modern pharmacy practice.

Benzodiazepines

Aged Care Homes

Two of our clients in Aged Care Homes have drafted a response outlining their perspective on the proposed change and these are attached to this submission.

Please refer to the attached responses from two of our ACF clients to this proposal

Prescriptions

The administrative demands in dealing with the addition of the benzodiazepines to Schedule 8 prescriptions would be significant. Not only the additional administrative workload for compliance with current regulatory standards, but the perhaps unforeseen frustration of the recent reforms to prescription management in the private hospital and aged care sectors. Mid 2013 will see a fifth Community Pharmacy Agreement (5th CPA) reform implemented which enables most schedule 4 PBS listed medicines to be claimed as PBS benefits directly from the patient's medication chart, rather than a separate prescription as is currently the case. However, Schedule 8 medicine claims will still require a separate PBS prescription to be supplied. One can, therefore, foresee the large additional administrative burden this will place upon all involved (prescribers, nursing staff and pharmacists), just when a lessening of this workload was envisaged.

3. Cost

Pharmaceutical Benefits Scheme (PBS)

On the basis of available national prescription data (from 2009) approximately 7.6million PBS prescriptions for benzodiazepines were supplied. Should this number of prescriptions be transferred to Schedule 8, the estimated cost to the PBS in additional dispensing cost would be approximately \$20 million per annum. This is based upon the current Schedule 8 additional fee of \$2.71 per item).

Clients

The use of benzodiazepines outside of the PBS is an area that should also be considered. Estimating use is rather more difficult than with the PBS and one could infer from available data that approximately 900,000 "private" prescriptions would be supplied annually. This represents an additional cost to consumers of at least \$2.5 million annually.

4. Equity of access and Quality Use of Medicines (QUM)

As a class of medication, some people may consider the benzodiazepines are not being used optimally within the Australian community. It must however be acknowledged that they are preferable to their predecessors; the barbiturates, as hypnotics, sedatives and anxiolytics. It is a concern that the use of an administrative lever to reduce the use of these medications in the community, may inadvertently lead to an increase in the use of other, potentially more toxic agents in their place.

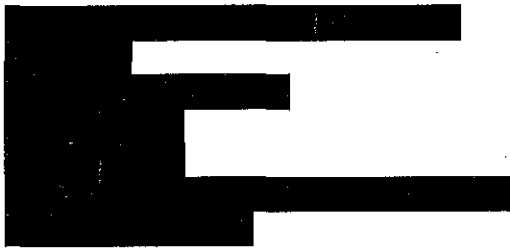
This could include the tricyclics antidepressants, mirtazepine (a newer agent that has some limited anxiolytic properties), certain antipsychotics, even some antihistamines with sedative properties. The potential toxicities of these agents would greatly outweigh those of the benzodiazepines they would potentially supplant. This may also place unwanted barriers to the appropriate use of these agents in community and institutional settings.

Benzodiazepines

One of the significant foundations of our National Medicines Policy includes the notion of the Quality Use of Medicines (QUM). By definition, this ensures medicine use is safe, efficacious, judicious and cost effective. The proposed change of scheduling of the benzodiazepine class of medications to schedule 8, would significantly impact on both the equity of access to optimal medications, as well as the Quality Use of Medicines for many Australians, both in the wider community and in the Aged Care setting.

The Haddad Pharmacy Group strongly suggests that any proposal to reschedule the benzodiazepines from schedule 4 to schedule 8 be rejected by the committee.

Yours sincerely,

A large black rectangular redaction box covering the signature area.



Resthaven

Benzodiazepines

ABN 79 976 580 833

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Paradise

Westbourne Park

COMMUNITY SERVICES

Limestone Coast

Marion

Murray Bridge & Hills

Northern

Onkaparinga

Paradise & Eastern

Respite for Carers

Riverland

Western

15 January 2013

The Secretary
Scheduling Secretariat
GP Box 9848
CANBERRA ACT 2601

Dear Sir/Madam

**RE: PUBLIC SUBMISSION, PROPOSED AMENDMENT: PROPOSAL TO
RESCHEDULE BENZODIAZEPINES FROM SCHEDULE 4 TO SCHEDULE 8
(REGULATION 42ZCZK, THERAPEUTIC GOODS REGULATION 1990)**

Resthaven Inc. welcomes the opportunity to provide the following comments to the proposed Amendment related to the rescheduling of Benzodiazepines from Schedule 4 to Schedule 8 medications.

Whilst the proposed amendment may provide a control measure for illicit use/misuse/abuse of benzodiazepine medications, it will create many significant unintended consequences for residential aged care facilities as well as community services.

Resthaven Inc. (South Australia) operates residential aged care facilities in ten locations, offering accommodation to more than 1,000 older people in independent living units, short term respite and high and low residential care.

In the community, Resthaven serves approximately 7,000 older people who access a range of in-home community care and support options to assist them to live independently and maintain social connections. Community services are offered throughout metropolitan Adelaide, the Adelaide Hills, Murraylands, Riverland and across the Limestone Coast.

Background:

Benzodiazepines, also known as "minor tranquillisers", are most commonly prescribed by medical practitioners to relieve stress and anxiety and to help people sleep. Common benzodiazepines include Diazepam, Oxazepam, Alprazolam, Nitrazepam and Temazepam. Benzodiazepines are produced by different drug companies using different trade names for the same medication.

Using benzodiazepines without a prescription from a medical practitioner, or selling or giving the medications to another person, is illegal. Legislation is in place against forging or altering a prescription or making false representation to obtain benzodiazepines or a prescription for these medications. Regular use of benzodiazepines can develop dependence and tolerance. Dependence on benzodiazepines can be psychological, physical, or both. The effects of benzodiazepines, as with any medication, depends on the amount taken and period of time over which use occurs. Use of any medication carries some risk as medications can produce unwanted side effects.

The Benzodiazepine group of medications are commonly prescribed for older people who require residential aged care and community care service, in an appropriate manner, by the treating General Practitioner, a treating Medical Specialist or an authorised Nurse Practitioner. The decision to prescribe these types of medications is assumed to be done with full consideration and review by the appropriate officer prescribing.

It is of note that these medications are also reviewed regularly through the Medicare Australia Residential Medication Management Review and Quality Use of Medicine reviews undertaken by an appropriately qualified Clinical Pharmacist in both residential and community care.

As benzodiazepines are more commonly prescribed than any current Schedule 8 medication, the inclusion of this group of medications to the Schedule 8 group poses a potential reduction in quality of care for the older person.

Impact on Residential Care Services:

- If the proposed change is implemented it will result in **significant** resourcing issues for Registered Nurses and care staff working in residential aged care facilities across all shifts. The change in practice will require two staff having to check every episode of administration of a benzodiazepine medication – regular and PRN (as required) orders. The biggest resourcing impact will be experienced during evening and night duty shifts when access to the Registered Nurse is significantly reduced.
- Reclassification of benzodiazepines will increase time taken to manage the delivery of medication from the pharmacy to the aged care facility, requiring counting at the time of delivery and 'checking in' of the delivered medications into the site's medication safe.
- The proposed change will have significant impact on the time taken for medication count of Schedule 8 medications that occurs at staff shift change. The number of medications requiring counting will significantly increase.
- The change in practice will have significant impact on medication storage. Regular benzodiazepine medication would have to be packed separately to other regular prescribed medications and stored accordingly. Medication storage facilities are currently at capacity with those medications already listed as Schedule 8.

Impact on Community Services:

- The organization has a protocol for a Home Support worker to, in the absence of family, collect and deliver Schedule 8 packed medications to a client's home. If benzodiazepines were reclassified to Schedule 8 medications this would place an enormous burden on the volume of related processes, staff time and service cost.
- Within our Community Services the Respite Centres currently need to access a Registered Nurse to administer Schedule 8 medications. With this proposed change and the potential to have a marked increase in Schedule 8 medications, Resthaven would require additional Registered Nurses across a 24 hour period. The current funding via the National Respite for Carers Program would not meet cost increases. Such an outcome would risk the viability of such services at all times and more particularly overnight and weekend services.
- The proposed change will impact credentialing and supervision of Home Support workers. Current Schedule 8 medications are managed using slow release medication delivery presentations. Inclusion of benzodiazepine medications as Schedule 8, with related regulations will require increased home visits by Registered Nurses.

In addition to the resourcing issues as a key challenge related to this proposed changes, are also the risks associated with the quality and timeliness of services provided. This unintended consequence of the changes to the Schedule for benzodiazepines, if not appropriately managed, will place older people at significant risk.

Resthaven Inc. strongly requests reconsideration of the proposed rescheduling of benzodiazepine medications to Schedule 8 classification.

Yours sincerely



Benzodiazepines

[REDACTED]

Concerns re Proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8.

Staff time;

There is already a reasonable amount of RN/EN time spent on counting current Schedule 8 medication stock levels at the beginning of each shift and the need to have x2 staff (RN/EN/credentialed PCW) counting for each administration of a Schedule 8 medication and documenting on the residents individual medication chart, the DDA Register and in the residents clinical notes. If this is to also be expected for Benzodiazepines then this will significantly increase staff workload and time. Spending more time administering these medications reduces the time the RN/EN/credentialed PCW has available for hands on clinical care (potentially reducing the ability to provide quality of care to frail elderly residents). The majority of Benzodiazepines are administered late evening and nocte when there is already minimal staff on duty. Facilities would possibly need to increase RN/EN hours to accommodate these requirements (increasing financial burden on organisations which are already facing difficult times with funding having been reduced via recent changes to ACFI rules).

Storage;

Some facilities already face difficulty with storage space for current schedule 8 medication due to the requirement of double locking system (i.e. double locked cupboard or locked cupboard in a locked medication room). This in turn will create increased financial burden on organisations having to increase storage space.

Regards,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Benzodiazepines

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16 January 2013

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Dear Sir/Madam,

I would like to submit my objection to the proposal to reschedule benzodiazepines from Schedule 4 to Schedule 8.

I am the CEO of APHS Packaging, a licenced medicine manufacturer. We repackage medications into patient specific compliance packs for community pharmacies located all over Australia, who then supply these dose administration aids to their predominantly elderly customers located either in residential care facilities or in their own homes.

Dose Administration Aids (DAA's) play a vital role in aiding consumers maintain their independence and reduce their risk of medicine misadventure, allowing them to remain in their own homes for longer. Once these patients do need to move into a residential care environment, DAA's continue their role in improving safe medicine outcomes, while also delivering very necessary productivity benefits for care staff in these facilities.

There is already a minimal risk of oversupply or overconsumption of benzodiazepines when they are delivered in a DAA format, as only the prescribed daily doses are available for each patient. If benzodiazepines are rescheduled from Schedule 4 to Schedule 8 there is no increased accountability in relation to their use in these consumers, as each individual dose is already fully accounted for and traceable - in the residential care environment a signed record of administration provides an even greater level of visibility.

If the proposed rescheduling proceeds, a significant additional cost increase will be incurred by our business, as a consequence of the additional administrative requirements and storage conditions for Schedule 8 medicines. This cost would need to be passed on to our client pharmacies, who would then incur their own additional costs as a consequence of the same additional requirements, with high likelihood that these costs will be ultimately be passed on to the end consumer.

Increasing the cost of medicines has been demonstrated to be a barrier to compliance, and if the cost to consumer of DAA's is increased this is likely to reduce current utilisation rates. Medication compliance issues make a significant contribution to hospitalisation rates, particularly in elderly patients, and government policy and funding has actively been seeking solutions, including the increased provision of DAA's, which help to address this. A change in scheduling will provide a significant barrier to increasing DAA uptake rates.

Benzodiazepines

Many states also require Schedule 8 medicines to be provided in a separate DAA to Schedule 4 or below medicines, requiring patients to have co-ordinate two DAAs. If benzodiazepines are moved from Schedule 4 to Schedule 8 this will generate a huge uplift in the number of consumers who need to manage two separate DAAs. As well as resulting in substantial cost increases in both preparation and administration, there is also a significant increase in the risk of administration errors occurring.

The proposed reschedule will undoubtedly have a consequence of increased costs and reductions in productivity, and also has the potential to increase the risk of medication misadventure in elderly patients via reducing their access to DAAs. As such, it is difficult to see that this change delivers a public health benefit and I would request that you do not support this proposal.

Yours sincerely



SUBMISSION RE *Proposed amendment to the Poisons Standard*

I write as an accredited pharmacist, having been accredited since August 2002. I have also worked in Aged Care Facilities (ACF), conducting RMMRs (Residential Medication Management Reviews) for some ten years.

I write to voice concern about the rescheduling of benzodiazepines from schedule 4 to schedule 8, particularly from the point of view of those involved in medication use in ACFs.

When I first commenced conducting what were then routine RMMRs there was considerable use, some inappropriate, of benzodiazepines in the aged care setting. Through my RMMR reports I provided education re the use of benzodiazepines and non-drug measures to manage insomnia, anxiety, behavioural problems etc to the nursing staff and also reinforced guidelines for appropriate use to resident's GPs. Over time I saw the use of benzodiazepines in the ACF context decline, so that generally they were only used when appropriate or very difficult to withdraw. In the ACFs in which I currently work this appears to have remained so.

I have recently discussed the issue of the rescheduling of benzodiazepines with the Director of Care at a local ACF. She was concerned at the increased work load and complexity of supply such a change would incur, especially since most use of benzodiazepines in this facility is "prn".

This particular ACF is in a regional area and it is becoming increasingly difficult to get appropriately qualified staff, especially registered nurses. The rescheduling means that stocks of benzodiazepines need to be counted/ checked at each staff change-over by two members of staff. When a benzodiazepine has to be administered it will also require a registered nurse finding another member of staff to accompany them to the one area (in quite a large facility) in which schedule 8 drugs are kept and then signing/ countersigning once the benzodiazepine has been administered to the resident. Since in this facility as I have already mentioned benzodiazepines are mostly given on a "prn" basis, that is when it is required by the resident, this may well be late at night or early morning when staff levels are lower.

The Director of Care could also foresee difficulties in contacting and getting a GP to visit and write the necessary prescription.

I understand the rationale behind the rescheduling but think that it will inconvenience and provide difficulties for those who aren't abusing this class of drug and as with narcotic analgesics probably do little to curb misuse/ abuse and redirecting of these drugs into illegal settings.

Benzodiazepines

I have conducted HMRs for patients who are using increasing doses and quantities of both narcotic analgesics and benzodiazepines. The GPs involved have found this useful as it adds weight to their advice to these patients.

I therefore urge you to reconsider this particular rescheduling and investigate other measures such as more prescriber education and promotion of more collaborative RMMRs and HMRs (Home Medicine Reviews) so that doctors, pharmacists and patients are working together to make best use of medications, including benzodiazepines.

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[REDACTED]

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