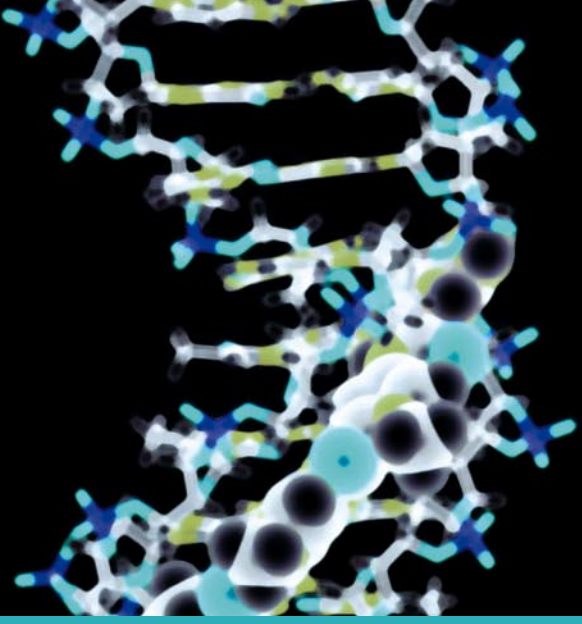
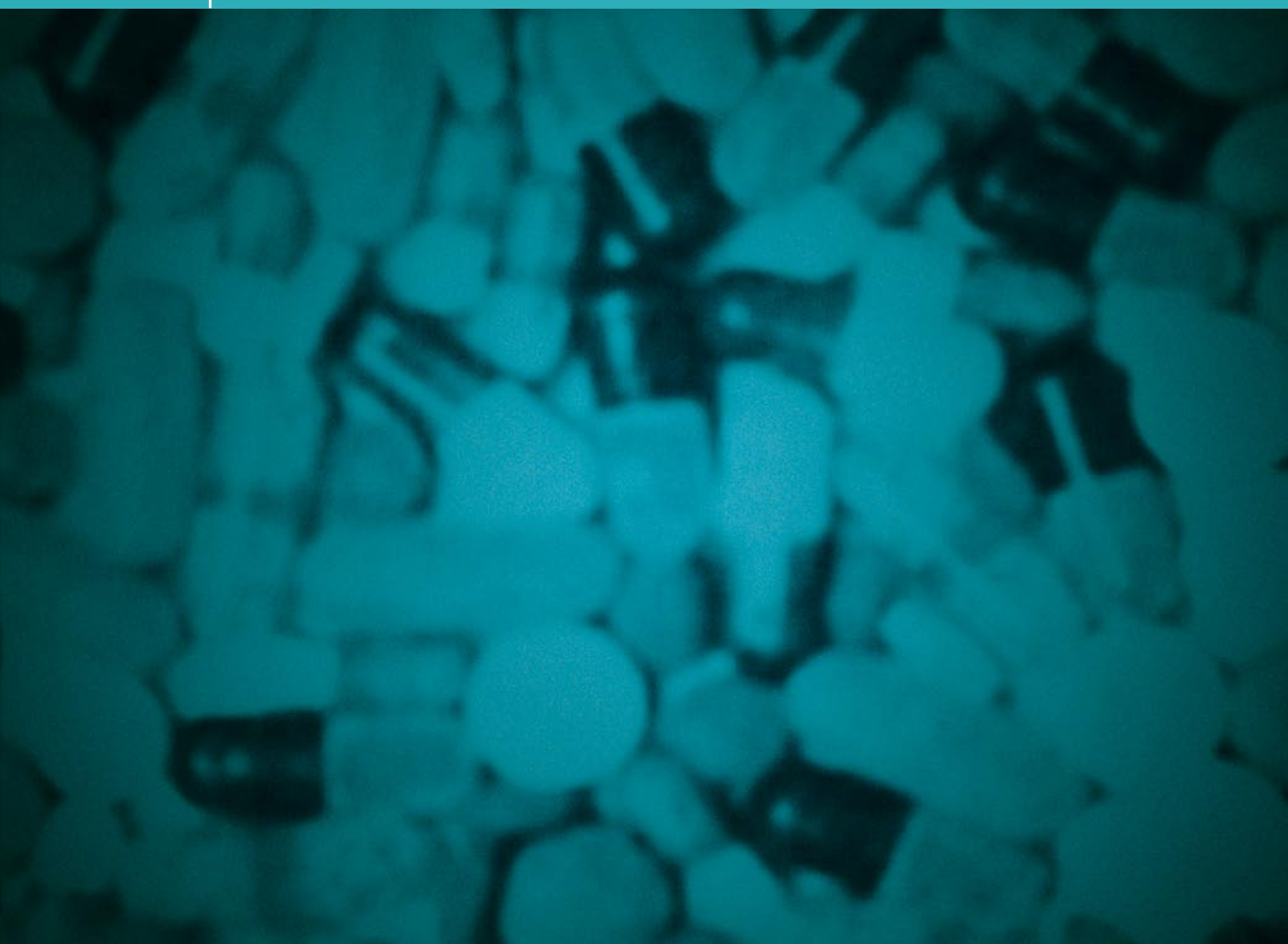


Drugs and
Crime Prevention
Committee

Inquiry into Misuse / Abuse of Benzodiazepines and other Pharmaceutical Drugs

Interim Report



PARLIAMENT OF VICTORIA

DRUGS AND CRIME PREVENTION COMMITTEE

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

Interim Report

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Drugs and Crime Prevention Committee

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Drugs and Crime Prevention Committee

Level 8, 35 Spring Street
Melbourne Victoria 3000
Phone: (03) 9651 3546
Fax: (03) 9651 3603
Email: sandy.cook@parliament.vic.gov.au
Website: http://www.parliament.vic.gov.au/dcpc

Drugs and Crime Prevention Committee

Members

Mr Johan Scheffer, M.L.C., *Monash Province* – Chair

The Hon. Robin Cooper, M.L.A., *Mornington* – Deputy Chairman

Ms Kirstie Marshall, M.L.A., *Forest Hill*

Mr. Ian Maxfield, M.L.A., *Narracan*

Dr. Bill Sykes, M.L.A., *Benalla*

The Hon. Sang Minh Nguyen, M.L.C., *Melbourne West Province*

Mr. Kim Wells, M.L.A., *Scoresby*

Staff

Ms Sandy Cook, *Executive Officer*

Mr Peter Johnston, *Senior Legal Research Officer*

Ms Michelle Summerhill, *Office Manager*

Consultants

Consultants from National Drug Reseach Institute, Curtin University (NDRI):

Professor Steve Allsop

Associate Professor Simon Lenton

Dr Susan Carruthers

Mr James Fetherston

Functions of the Drugs and Crime Prevention Committee

The Victorian Drugs and Crime Prevention Committee is constituted under the *Parliamentary Committees Act 2003* (Vic) as amended.

Section 7

The functions of the Drugs and Crime Prevention Committee are, if so required or permitted under this Act, to inquire into, consider and report to the Parliament on any proposal, matter or thing concerned with:

a. the use of drugs including the manufacture, supply or distribution of drugs;

b. the level or causes of crime or violent behaviour.

Terms of Reference

The Governor in Council, under section 4F of the Parliamentary Committees Act 2003, requests that the Drugs and Crime Prevention Committee of Parliament inquire into and report to Parliament on the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria. In particular, the Committee is required to:

1. Examine the nature, extent and culture of the misuse/abuse of benzodiazepines and other forms of pharmaceutical drugs;
2. Examine the short and long-term consequences/harms of the abuse/misuse of benzodiazepines and other forms of pharmaceutical drugs;
3 Examine the relationship between benzodiazepines and other forms of pharmaceutical drugs and other forms of licit and illicit substance use;
4. Review the adequacy of existing strategies for dealing with benzodiazepines and other forms of pharmaceutical drugs misuse/abuse;
5. Recommend best practice strategies to address the issue of benzodiazepines and other forms of pharmaceutical drugs, including regulatory, law enforcement, education and treatment responses;
6. Examine national and international legislation, reports and materials relevant to the issue.

Dated: 17 January 2006

The Committee commenced the Inquiry in May 2006.

Chair's Foreword

In January 2006 the Drugs and Crime Prevention Committee was asked to conduct an Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria. At that time the Committee was fully occupied with the completion of its previous report on its Inquiry into Strategies to Reduce Harmful Alcohol Consumption and was unable to commence work on the new inquiry until May 2006.

The terms of reference for the Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria required the Committee to examine the nature, extent and culture of the misuse/abuse of these drugs and to look at the short and long-term impacts of harms. The Committee was also asked to study the relationship between these drugs and other forms of licit and illicit substace use, review existing strategies for dealing with their misuse/abuse and to recommend ways to address such abuse through better regulation, law enforcement, education and treatment responses.

Once again, the Committee found it was dealing with a complex task that needed more time than was available. As a result, it was agreed that the Committee would prepare an Interim Report and that this would be tabled in the Parliament in August 2006.

The Interim Report takes up the issues raised in the Terms of Reference and presents sufficient background information to introduce the reader to how benzodiazepines and narcotic analgesics (opioids) are used therapeutically, the extent to which they are being misused and the adverse consequences of this misuse. It presents an account of the reasons people misuse these kinds of drugs and the patterns of such misuse and offers, what the Committee hopes will be a useful explanation of legal and regulatory issues surrounding use and misuse of pharmaceutical drugs.

The Interim Report also gives an overview of how the production, prescription and retailing of these drugs is managed by medical officers and pharmacists and discusses how information about these pharmaceuticals is provided and how the public is educated so as to reduce harm. Finally, attention is given to treatment issues relating to prescription drug abuse. In particular, the Interim Report notes the paucity of options with regard to specific treatment modalities for benzodiazepine abuse.

During the course of its investigations the Committee realised that there are many issues pertaining to pharmaceutical abuse that need to be explored in greater detail. The complexity of these issues has not been able to be canvassed sufficiently in an Interim Report of this nature. For this reason the Committee believes the evidence warrants the Drugs and Crime Prevention Committee

undertaking ongoing work in this area by completing a Final Report for this Inquiry during the term of the 56th Parliament. Consequently, the Interim Report sets out the issues that a future comprehensive inquiry and Final Report would need to focus upon.

The Committee has received considerable evidence indicating that there are serious gaps in knowledge about the extent and consequences of prescription and pharmaceutical drug abuse in Victoria. For example, it is evident that the current information available to prescribers and dispensers and monitoring systems relating to benzodiazepines and other forms of pharmaceutical drug use and misuse are not optimal. This limits the ability of prescribers and dispensers to identify high-risk behaviour (for example, 'doctor shopping') in relation to individual patients and to patterns of use in any given community. Such limitations of the current systems are also believed to reduce the capacity of prescribers, dispensers and policy makers to more generally develop effective prevention and other responses to pharmaceutical drug misuse. These have also been identified as a barrier to effective management of individual patients. The inadequacy of current systems was consistently raised by a significant number of those individuals and organisations that provided evidence and/or submissions to the Inquiry. While it is recognised that there are practical challenges and privacy issues inherent in implementing an effective model, the current systems are regarded as barriers to effective management.

It is also evident that information provision to both patients and professionals is in need of improvement, despite some excellent efforts by various organisations and professional bodies. In particular, it was noted that there appeared to be no systematic management of information development and dissemination, resulting in gaps in access to quality information and education. For example, access to information about the misuse of narcotic analgesics (other than methadone and buprenorphine) was limited.

The Internet is providing new challenges that need to be monitored, considered and responded to. For example, people can access medications via the Internet, legitimately and illegitimately, which has the potential to contribute to changes in the levels, patterns and nature of pharmaceutical drug misuse. However, individuals can also use the Internet to access information about how to misuse pharmaceutical drugs, in addition to information about prevention, harm reduction and treatment initiatives.

This Inquiry largely addressed the needs of people affected by pharmaceutical misuse (consumers and their families), medical staff, pharmacists, and to a lesser extent groups such as local government. However, it may also be appropriate to consider the needs of other groups in more detail, for example the education and training needs of police. This could include considering the relevant procedures to follow to respond appropriately to forgery, diversion and intoxicated behaviour.

There is also a need to consider the role of pharmaceutical companies. While pharmaceutical drugs are used widely for legitimate purposes, pharmaceutical companies have a responsibility to reduce the misuse potential of their products. A concern is that where, as in the United States, regulators put pressure on companies to do this, the companies may respond with 'relatively easy' actions. These may include measures such as providing information and training for doctors in dealing with 'doctor shoppers' rather than changing the formulations of their drugs to make them less dangerous or harder to misuse. The responsibility and role of pharmaceutical companies with regard to misuse of their products must therefore be taken into account.

It is also important to ensure involvement of user groups and other representatives of consumers. It is important that the full Inquiry should attempt to ensure this perspective is well canvassed.

While it is evident that there may be a need to constrain or restrict access to some pharmaceutical drugs, it will also be important to consider the likely unintended adverse consequences of further restrictions on pharmaceutical drug misuse. Some sources have indicated that pharmaceutical drug misuse may result in lower levels of harm than occurs with the use of some 'street drugs'. This is a complex issue, but one that should be more comprehensively addressed in the full Inquiry.

The present Inquiry focussed on benzodiazepines and narcotic analgesics. The Committee notes, however, evidence that the misuse of other pharmaceuticals such as non-prescription or over the counter drugs, antidepressants and impotence drugs such as Viagra is also problematic and worthy of future investigation. It may be that these other classes of pharmaceuticals should also be considered in any extension of this Inquiry.

The above account relates to some of the most important issues flagged in this Interim Report. However, these are by no means the only ones that the Committee has considered. At the end of each chapter a list of questions and issues for future consideration will inform the progress of the remainder of the Inquiry.

During its investigations the Committee gathered valuable evidence from a number of individuals and organisations that made submissions and/or gave evidence to the Committee at Public Hearings or other meetings with the Committee. I would especially like to thank those individuals who came forward to share their personal or family experiences of struggle with the terrible effects that these pharmaceuticals drugs can have. The Committee found these personal insights extremely valuable and admired the courage, strength and determination of these fine people.

I would like to thank my fellow committee members Hon Robin Cooper M.L.C. (Deputy Chair), Kirstie Marshall M.L.A. (Forest Hill), Ian Maxfield M.L.A. (Narracan), Bill Sykes M.L.A. (Benalla), Hon. Sang Minh Nguyen (MLC Melbourne West Province) and Kim Wells M.L.A. (Scoresby). I give special

thanks to Robin Cooper for his strong support and for his always remarkable attention to both the detail of the technical content of this report as well as to the bigger picture issues.

I would also like to thank Professor Steve Allsop, Associate Professor Simon Lenton, Dr Susan Carruthers and Mr James Fetherston of the National Drug Research Institute, Curtin University of Technology for their valuable work as consultants to this Inquiry.

This is the final Report of the Drugs and Crime Prevention Committee for the 55th Parliament and, on behalf of the members of the Committee, I pay tribute to the extraordinary work of the Drugs and Crime Prevention Committee research and support team: Executive Officer Ms Sandy Cook, Senior Legal Research Officer, Peter Johnston and Office Manager, Michelle Summerhill. Their dedication, research expertise, breadth of knowledge and intellectual acumen enables the Drugs and Crime Prevention Committee to achieve the recognition and universal respect it does both at home and internationally. Once again the Committee also wishes to thank Chris Watson from zapwhizz.com.au for his professional layout of the Reports, Matt Clare of Mono Design for his creative and striking cover designs and Phil Balzer of TDC3/Mercury Printeam for his excellent service in printing the reports. Finally, as always, the Committee is grateful to Mignon Turpin for her exceptional work in editing all the Committee's Reports. Her expertise, attention to detail and unstinting commitment has been outstanding.

Johan Scheffer M.L.C.

Chair

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List of Abbreviations

ACC	Australian Crime Commission
ADEC	Australian Drug Evaluation Committee
ADF	Australian Drug Foundation
ADHD	Attention Deficit Hyperactivity Disorder
ADIN	Australian Drug Information Network
ADRAC	Adverse Drug Reactions Advisory Committee
AHMAC	Australian Health Ministers' Advisory Council
AIHW	Australian Institute of Health and Welfare
AMA	Australian Medical Association
APAC	Australian Pharmaceutical Advisory Council
ARCOS	Automation of Reports and Consolidated Orders System
ARGOM	Australian Regulatory Guidelines for Over The Counter Medicines
ARGPM	Australian Regulatory Guidelines for Prescription Medicines
ARTG	Australian Register of Therapeutic Goods
ASSAD	Australian Secondary Students' Alcohol and Drug survey
AUSTFA	Australia–United States Free Trade Agreement
BCS	British Crime Survey
CALD	culturally and linguistically diverse
CASA	National Center on Addiction and Substance Abuse (USA)
CMC	Case Management Committee
CMEC	Complementary Medicines Evaluation Committee
CMI	Consumer Medicine Information
CNS	central nervous system
CPA	Community Pharmacy Agreement
CREDIT	Court Referral and Evaluation for Drug Intervention and Treatment Program
DEA	Drug Enforcement Agency
DHS	Department of Human Services

DN	Dextropropoxyphene napsylate
DoHA	Department of Health and Ageing (Commonwealth)
DPCS Regulations	Drugs Poisons and Controlled Substances Regulations
DPCSA	*Drugs, Poisons and Controlled Substances Act*
DPRG	Drugs and Poisons Regulation Group
DPU	Drugs and Poisons Unit (Department of Human Services Victoria)
DUMA	Drug Use Monitoring in Australia
DUSC	Drug Utilisation Sub-Committee
DVA	Department of Veterans Affairs
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
FDA	Food and Drug Administration
GABA	gamma-aminobutyric acid
GMP	Good Manufacturing Practice
HIC	Health Insurance Commission
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDRS	Illicit Drug Reporting System
IDUs	injecting drug users
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IHRA	International Harm Reduction Association
MBS	Medical Benefits Scheme
MCDS	Ministerial Council on Drug Strategy
MDMA	Methylenedioxy-methylamphetamine
MEC	Medicines Evaluation Committee
MMT	Methadone Maintenance Treatment
MPBV	Medical Practitioners Board of Victoria
MRD	Methadone-related death
MSC	Medicines Scheduling Committee
MTF	Monitoring the Future
NBV	Nurses Board of Victoria

NCCTG	National Coordinating Committee on Therapeutic Goods
NDLERF	National Drug Law Enforcement Research Fund
NDPSC	National Drugs and Poisons Schedule Committee
NDRI	National Drug Research Institute
NDS	National Drug-control System
NDSHS	National Drug Strategy Household Survey
NHS	National Health Service
NMP	National Medicines Policy
NPA	National Prescription Audit
NSDUH	National Survey on Drug Use and Health
NSP	Needle and Syringe Programs
OHS	Occupational Health and Safety
OTC	Over the counter (medicines)
PADS	Prescription Abuse Data Synthesis
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PDI	Party Drugs Initiative
PDMP	Prescription Drug Monitoring Programs
PGA	Pharmacy Guild of Australia
PPA	Prescription Pricing Authority
PSA	Pharmaceutical Association of Australia
PSC	Poisons Scheduling Committee
PSR	Professional Services Review scheme
PTD	psychotherapeutic drugs
QUM	Quality Use of Medicines
RACGP	Royal Australian College of General Practitioners
RPBS	Repatriation Pharmaceutical Benefit Scheme
SAMHSA	Substance Abuse and Mental Health Services Administration
SSRIs	Selective Serotonin Reuptake Inhibitors
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TAC	Transport Accident Commission

TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code
TGO	Therapeutic Goods Order
TGVA	*Therapeutic Goods (Victoria) Act*
TPG	Talc Pulmonary Granulomatosis
TRANX	Tranquilliser Recovery and New Existence
UNDCP	United Nations International Drug Control Program
UNODC	United Nations Office of Drugs and Crime
VIFM	Victorian Institute of Forensic Medicine
VYADS	Victorian Youth Alcohol and Drugs Survey
WHO	World Health Organization
YSAS	Youth Substance Abuse Service

1. Introduction and Background to the Inquiry

> *At work I am Mary Smith the pathology nurse and I get along well with my colleagues. Going home can be a nightmare. I immediately think of medication, the minute I start driving home. I have to push myself not to look at doctors' surgeries. In the tram on the way down here, to be honest, I see medical clinics. Most people see milk bars or lollies. No, I see medical clinics. It is something that is so frighteningly there, right in my face. You are almost counting medical clinics along the street. It is very frightening.*[1]

> *My life revolved around getting Panadeine Forte and pethidine, and that was all that mattered. I had come to the point where I never left the house unless it was to go and see my doctor or to go to a hospital to get pethidine. That is all it was. It had been like that for about four years. I had not been to my local shopping strip for four years. I had not seen my neighbours for four years, and I was terrified. I would make sure that whenever I left the house there would be nobody around so I would not have to see anybody.*[2]

The bleak and graphic consequences of drug dependency, as described in these women's accounts, are most commonly associated with illegal drugs, such as heroin or amphetamines. It may be surprising to many, therefore, to learn that the drugs responsible for the above distressing descriptions could be regular prescription medicines. The harm that is associated with benzodiazepines and other pharmaceutical drugs has, to some extent, been long neglected. Indeed, many people would not consider such drugs to be an important focus of any attempt to prevent and respond to 'drug problems'.

As one woman speaking to the Committee explained:

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1 'Mary', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

2 'Anne', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

> I went and had a haircut last Friday and there were not too many people in my hairdresser's, so I mentioned that I was coming here today. They said, 'Drugs and crime. What's all that about?' So I just let it slip and we had a discussion. They said, 'Yes, but that's not you'. I said, 'Yes. I'm a recovering drug addict'. 'Really?' I said, 'Yes'. 'Yes, but not you'. I said, 'Yes'. They said, 'But what did you take?' I said, 'Narcotics: codeine, pethidine, benzodiazepine, Valium'. 'Yes, but that's not really drugs.' I said, 'Yes, it is'. They said, 'But that's not really – you wouldn't call that a drug addict'. I said, 'Well, what do you mean by a drug addict' Again, it came straight back to somebody with a needle hanging out of their arm, somebody who is addicted to cocaine, marijuana, somebody who is a street person, somebody who is dirty and unclean; that is a drug addict. Drug addicts do not look like me or you.[3]

This perception is not restricted to those who have little experience with drug-related issues. It is also indicative of how some people who are well informed about the issues surrounding illegal drug use often underestimate the risks associated with the misuse of pharmaceutical drugs:

> People who inject drugs are reasonably well informed of key risks associated with heroin use. Amongst our service users, benzodiazepines are perceived to be less harmful and safer than heroin use. There is a lack of awareness of how easy it is to develop a dependency on benzodiazepines, and how serious this dependency can be. Some education has been undertaken to increase users' awareness of overdose, however in general there is still a lack of understanding regarding a drug's length of action (the half life) and interactions between opiates and benzodiazepines.[4]

The Drugs and Crime Prevention Committee recognises the significant health benefits that arise from safe and effective prescription and use of benzodiazepines and other pharmaceutical drugs. However, substantial concern has been expressed by members of the community and individual professionals and professional organisations regarding the significant harms that can arise from misuse of these medicines. Various coronial inquiries have noted that benzodiazepines and other pharmaceuticals have been identified in a significant proportion of drug-related deaths.[5] The distress that this has caused to the families and friends of those affected by such drug use was evident in a number of submissions and statements made to the Inquiry:

> I have a 16-year-old daughter who is currently finding it very difficult to come to terms with a mother that has had an addiction. She left me a note near the kettle the night before last – it was rather sad really – saying that she has had

3 'Anne', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

4 Submission made by Western Region Health Centre to the Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

5 See Chapter 4.

> to lie to people to cover up things that I have done in the past. I have tried very hard to make amends with Jane. I am finding a lot of difficulty talking to her at the moment – (a) that she is 16; (b) I cannot justify the lies in the past. All I have done is to try to be up-front with her, and talk about the addiction and the dependency. But at the moment she is a very angry 16-year-old. I currently have a broken sliding door at the back. She is a very angry young girl.
>
> I would like her to get help somewhere but at the moment it is all me. She sees herself as a reflection of me. I find the whole thing at the moment is very confronting. That is why I am having a lot of difficulty staying away from, or trying to keep away from, medication. It is so tempting to go back and block out that whole emotional thing that I can feel now occurring. My only outlet at the moment is work.[6]

Medical services have reported their concerns about vascular and other damage that arises from injecting pharmaceuticals not manufactured for that purpose, often resulting in severe damage to extremities, sometimes resulting in amputation. Damage to other organs can occur and cerebral strokes are also a risk (see Chapter 4). Recent examinations of drug-related deaths have indicated that there is a need to review strategies to prevent such misuse.[7] Police, doctors, pharmacists and statutory bodies invest much time in deterring and detecting fraudulent behaviour that is associated with acquiring pharmaceuticals for misuse. Pharmaceutical misuse can impact on the wellbeing of the broad community and local governments can have a role in preventing and responding to related problems.

These are challenges and problems that are experienced in most Australian states and territories, and indeed in many other countries in the world (for example, see National Center on Addiction and Substance Abuse at Columbia University 2005). These observations lead to the conclusion that it is pertinent to undertake an Inquiry to assess the nature and extent of any problem in Victoria, and to review current and potential effective responses to any harms that exist for individuals and the broader community.

Putting prescription drug misuse in context

Modern medicine relies on an increasing array of drugs or medications. Many of these are controlled, either through limited access by prescription from a medical practitioner or dentist and/or being limited to supply by a pharmacist. Others are more freely available through a variety of outlets.

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6 'Mary', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

7 See *Heroin-related overdose project*, Inquests into the deaths of David Borg, David Eberhardt, Sally Jessup, Clinton McLeod, Baskel Summut and Matthew Try, State Coroner's Office, Victoria, April 2000.

The availability of medicines is controlled because in addition to the intended benefits there are sometimes unintended adverse consequences. These consequences can arise if the medication is used outside guidelines for safe and effective use (for example, if overused or underused); used in conjunction with other drugs (polydrug use can reduce the effectiveness of specific drugs, thus interfering with treatment and increasing the risks of adverse consequences); used by people who could be at elevated risk of harm because of individual characteristics (for example, some people are allergic to certain medicines, or health conditions render a particular course of drug use dangerous).

Many drugs have psychoactive properties, defined by the World Health Organization (WHO) as follows: 'A psychoactive substance is one that, when ingested, alters mental process – that is thinking or emotion' (WHO 1994, p.53). Drugs with psychoactive properties include alcohol, marijuana, heroin and cocaine and a range of medications. Examples of the latter include benzodiazepines (eg. prescribed for anxiety or sleep disorders), antidepressants (eg. prescribed for severe mood disorders), opioids (eg. prescribed for pain management) and amphetamines (eg. prescribed for the management of Attention Deficit Hyperactivity Disorder (ADHD)).

Patients who have been prescribed such drugs as a legitimate component of their treatment can develop tolerance and dependence, requiring larger doses to bring about the intended or desired effect and continued doses to avoid the discomfort of withdrawal. As a consequence, some patients who may originally have been prescribed these drugs may eventually seek out these drugs for illegitimate purposes. However, there are other reasons why people might seek to illegitimately access and use prescription drugs. These include:

- **Iatrogenic dependence**: that is, they have become psychologically and/or physiologically dependent as a consequence of their treatment, which has now been completed;
- **Self-medication**: this could be self-medication of a medical condition without formal skilled medical intervention. Sometimes people can use drugs in an attempt to endure otherwise intolerable circumstances. For example, people may use central nervous system depressants such as opioids or benzodiazepines in an attempt to dull emotional pain related to past trauma and/or current circumstances. Such use can nevertheless be very risky.
- **Dealing with withdrawal symptoms**: pharmaceutical medications may be used illicitly to self-medicate adverse consequences of other drug use (for example, central nervous system depressants may be used to try to alleviate withdrawal or 'crash' symptoms that arise from heavy amphetamine use);
- **Drug substitution**: for example, if there is a shortage in the supply of one drug in the market, a drug user may substitute with another that has the same or similar effect. Thus, the recent heroin shortage has been

associated with an increase in diversion and misuse of drugs such as benzodiazepines and prescribed opioids;

- **Enhancement of other drug use**: for example, some individuals will take a controlled medication in combination with another drug to enhance or extend the overall desired effects. This can substantially increase the risk of adverse outcomes, as indicated by the significant proportion of fatal heroin overdoses where benzodiazepines have been detected;
- **Performance enhancement**: for example, some stimulants are used to enhance performance in social and employment situations;
- **Use by sexual predators**: for example, flunitrazepam (a benzodiazepine) has been added to drinks (drink spiking) or otherwise administered to an unsuspecting individual to assist in sexual assault; and
- **Use as a street currency**: many pharmaceutical drugs are sold on the black-market, thereby creating direct or indirect currency for the person who has obtained them.[8]

An individual may obtain pharmaceuticals for misuse through a number of ways including:

- Stealing, forging or altering prescriptions, which are then used to unlawfully obtain the drugs;
- Burglary of surgeries and pharmacies;
- Through 'doctor shopping' (presenting to several doctors and obtaining prescriptions for imaginary or exaggerated symptoms);
- Poor prescribing practices, such as prescribing larger quantities than are needed for managing the patient's conditions, providing an opportunity for the patient to sell the excess to others;
- Purchasing on the black market;
- Purchasing over the Internet;
- Health workers self-prescribing or otherwise misappropriating through work; and
- Opportunistic means (for example, from family members or friends who have been legitimately prescribed these medications).

These methods are discussed to varying degrees throughout this Interim Report.

The variety of ways in which these drugs are obtained indicates that preventing pharmaceutical misuse will require responses at several levels, including engaging national and state statutory bodies, professional boards and organisations, and implementing responses through law enforcement, health and community services.

8 These reasons for use are discussed at greater length in Chapter 5 of this Interim Report.

Why the concern?

The misuse of pharmaceuticals is a concern for several reasons. Many of the drugs that are misused are subsidised by the Australian Government through the Pharmaceutical Benefits Scheme (PBS), so widespread misuse can add a direct and substantial burden to the health budget, for no legitimate purpose or benefit. Use of these drugs outside of quality medical management can also result in a variety of adverse physical and mental health outcomes. Sometimes the drugs are used in doses or in a manner that creates significant risks to the individual. For example, many of these drugs are injected, even when they are not designed to be consumed in this manner, causing substantial problems such as vascular damage. They may also be used in conjunction with other (often illegal) drugs, significantly increasing the risk of fatal and non-fatal overdose. Maintenance of dependence through pharmaceutical misuse can create substantial harm and distress for individuals, families and the whole community, who sometimes mistakenly believe that a medicine is relatively low risk, as revealed by the following contribution to the Australian Drug Foundation website 'Somazone'.

> …the thing is you think that just because a drug isn't from the street or isn't illegal it is fine to take. I thought because a doctor gave me the tablets I couldn't become addicted or harmed but that isn't the truth. It's far from the truth; I thought I was safe taking those drugs but I was so wrong.[9]

Misuse of benzodiazepines, especially when combined with alcohol, can create an increased risk of aggression and violence. This in turn creates risks for police and treatment service providers who assist those who abuse these drugs. A submission sent to this Inquiry from the mother of a son who struggled with benzodiazepine dependence eloquently pointed out that the problems facing both the person misusing the drugs and their families go beyond the physical or medical consequences of their addiction:

> Benzos combined with alcohol or heroin are a dangerous mix both physically to the body but also affect the ability to make decisions, to discern danger and to discern actions…many actions in crime are made under this influence and are made spontaneously as drug combination appears to take away inhibitions and impulse control. These drugs long term and in large quantities also appear to take away memory both short term and long term.
>
> Getting free of these drugs has been harder than getting free of heroin for my son. Being "pilled out" has caused more legal problems for my son and his friends.[10]

9 Submission from the Australian Drug Foundation to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

10 Submission from Ms Margaret Quon to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

On the other hand, any attempt to prevent pharmaceutical misuse must consider the tension that exists between their legitimate and illegitimate use. A discussion on prescription drugs must take into consideration that when these drugs are used as intended as part of quality medical care, they can make a positive contribution to the wellbeing and health of many community members who are legitimately prescribed them and take them as indicated. Quigley (2001) sums up this challenge neatly, and while his comments are focussed specifically on benzodiazepines they are pertinent also to concerns about all types of pharmaceutical drug misuse:

> Benzodiazepine regulation is a highly challenging task, obliging us to come to grips with the determinants of community mental health, the role of general practitioners, the logic of the pharmaceutical industry and the dynamics of illicit drug markets. Sedative drugs play a range of roles in society, and display varying degrees of safety and legitimacy, depending on source, mode of utilization, social context and many other factors…
>
> Any simplistic attempt to restrict availability of a compound is liable to have negative therapeutic implications for legitimate patients, while the effect of regulation on street drug cultures cannot be predicted in advance (Quigley 2001, p.333).

Terms of Reference

In January 2006 the Drugs and Crime Prevention Committee was requested by Governor in Council to inquire into and report to Parliament on the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria. In particular, the Committee is required to:

1. Examine the nature, extent and culture of the misuse/abuse of benzodiazepines and other forms of pharmaceutical drugs;
2. Examine the short and long-term consequences/harms of the abuse/misuse of benzodiazepines and other forms of pharmaceutical drugs;
3 Examine the relationship between benzodiazepines and other forms of pharmaceutical drugs and other forms of licit and illicit substance use;
4. Review the adequacy of existing strategies for dealing with benzodiazepines and other forms of pharmaceutical drugs misuse/abuse;
5. Recommend best practice strategies to address the issue of benzodiazepines and other forms of pharmaceutical drugs, including regulatory, law enforcement, education and treatment responses;
6. Examine national and international legislation, reports and materials relevant to the issue.

The work of the Committee

An Interim Report

While the Committee received this Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria on 17 January 2006, it was not possible to commence the Inquiry until after it had tabled its Final Report for the Inquiry into Strategies to Reduce Harmful Alcohol Consumption on 22 March 2006. The Terms of Reference for the new Inquiry are extremely wide-ranging. In addition, the initial research undertaken by the Committee indicated that the issues raised could not be adequately dealt with in the time available. For these reasons the Committee has decided to table an Interim Report for this Inquiry before compiling its Final Report and making further recommendations.

The purpose of this Interim Report is primarily to highlight the scope and complexity of the issues to be addressed. It also aims to provide an overview of the academic and non-academic literature, outline the major legal and regulatory frameworks governing drugs and medicines control, and review some of the policies and programmes currently addressing the misuse/abuse of benzodiazepines and other pharmaceutical drugs in Victoria and other Australian jurisdictions. Finally, the Interim Report will raise specific questions and issues that need further consideration before the Committee can conclude its deliberations.

The research process

At the outset the Committee engaged the National Drug Research Institute (NDRI), Curtin University of Technology, as the consultant to the project.

With the invaluable assistance of NDRI the Committee has embarked upon preliminary research in order to canvass the issues and receive input and information from the many individuals, agencies and organisations that have a stake or interest in the issues raised in the Terms of Reference.

The Committee called for written submissions in *The Age* and *Herald Sun* on 1 April 2006. Letters inviting submissions to the Inquiry were sent to all local councils and shires in Victoria and key government and non-government agencies in Victoria and interstate. In all, the Committee received 28 written submissions.[11]

The Committee also conducted public hearings in Melbourne on 19 and 20 June 2006 and 13 July 2006. In total, the Committee received formal oral evidence from 20 witnesses.[12] In addition, Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services (DHS) Victoria, provided the Committee with an extensive briefing on 29 May 2006

11 For a list of submissions received see Appendix 1.

12 For a list of witnesses who gave oral evidence to the Committee at meetings or public hearings see Appendix 2.

and supplied a vast array of government and academic publications. The Committee is most appreciative of his contribution.

In conducting the Inquiry, the Committee has also undertaken a comprehensive review of the literature on the misuse and abuse of benzodiazepines and other forms of pharmaceutical drugs in Australia and overseas. The search included published, unpublished and web-based literature. The process involved using search engines such as Medline, Austlii, Lawlink, APAIS, CINCH Health and Medical Complete, ProQuest Social Science and Google Scholar Science Direct MedLine. Key references identified by those who made submissions to the Inquiry were also accessed if they had not already been identified in the formal search process. In addition, the websites of key national and state statutory bodies (for example, Medicare Australia, the Therapeutic Goods Administration (TGA), DHS Victoria) and professional organisations (for example, Royal Australian College of General Practitioners, Pharmaceutical Society of Australia) were reviewed for any literature, regulations and clinical and practice guidelines on drugs under consideration in this Inquiry.

The Committee is most appreciative of the time, effort and valuable contribution that all the individuals and organisations have made during the progress of this Inquiry. The submissions, briefings and public hearings have provided insights into the excellent work of various community and government organisations and valuable knowledge about what has turned out to be an extremely complex issue.

Which drugs to include

In Australia, the most commonly misused pharmaceuticals are painkillers/analgesics, benzodiazepines, narcotic analgesics, the stimulants methylphenidate (Ritalin) and dexamphetamine, and performance enhancing drugs such as steroids (Australian Institute of Health and Welfare 2005a).

This Interim Report, however, will focus only on the prescribed drugs that are captured under the broad headings of benzodiazepines and the narcotic analgesics. The reasons for so doing are threefold.

First these drugs and medicines, when used inappropriately or misused, not only result in serious physical damage and medical problems, they may also cause grave legal and social problems for the individual, their families and the broad community.

Second, given the enormous body of literature and research that has been produced with regard to *both* benzodiazepines and narcotic analgesics, it is certainly appropriate that this Interim Report should be limited to covering these groups of drugs only.

Finally, the other groups of drugs that may be loosely grouped under the Inquiry's Terms of Reference and the broad rubric of *pharmaceutical drugs* are not appropriate to consider at this stage for two main reasons. First, they may have been exhaustively examined by this Committee in other contexts, for example

the illicit use of pseudoephedrine to manufacture amphetamines was examined in the extensive report on amphetamines recently completed by the Drugs and Crime Prevention Committee and thus will not be covered here.

The second reason is that other groups of pharmaceutical drugs may warrant more extensive consideration than the time available for this Interim Report permits. The drug groups that could fall into this category include:

- The prescription and use of Ritalin and dexamphetamines for the treatment of ADHD;
- Over-the-counter drugs (for example, some pain and cold remedies and analgesics);
- Other central nervous system depressants such as ketamine and the barbiturates;
- Drugs used in sport, including some anabolic steroids; and
- The misuse of antidepressants, including both tricyclics and Selective Serotonin Reuptake Inhibitors (SSRIs).

Limiting the groups of drugs that the Committee will be covering in this Interim Report by no means suggests that the issues raised by the misuse of the drugs in the above list are unimportant. On the contrary, the misuse of such drugs is an emerging issue and is something that may best be covered when the Drugs and Crime Prevention Committee undertakes the remainder of the Inquiry.

A further note on the drugs covered in this Interim Report

Although covered in more detail in later chapters (see Chapters 2 and 4) it is worthwhile considering briefly the nature of the drugs covered in this Interim Report:

- **Benzodiazepines** are a group of depressant drugs, referred to as hypnotic sedatives or tranquillisers, initially developed as a safer alternative to barbiturates. They are most commonly used to treat stress, anxiety and panic disorders and sleeping disorders. They are sometimes used in the treatment of alcohol dependence. The following are examples of the wide variety of benzodiazepines that are available, with examples of the more familiar trade names in brackets: temazepam (Normison, Temtabs); triazolam (Hacion); bromazepam (Lexotan); oxazepam (Serepax); alprazolam (Xanax); nitrazepam (Mogadon); flunitrazepam (Rohypnol). Benzodiazepines, when used in legitimate treatment, are generally taken orally or injected, depending on the form in which they are prescribed.
- **Narcotic analgesics** are depressant drugs used in pain management and sometimes in the treatment of opioid dependence (for example, to assist in drug withdrawal or as part of drug maintenance treatment). The following are examples of narcotic analgesics: morphine, codeine phosphate, oxycodone, methadone, buprenorphine and pethidine. Narcotic analgesics, when used in formal treatment, are most commonly

taken orally or injected, depending on the form in which they are prescribed.

A note on terminology

A number of terms have been used in this Interim Report. Many of these have highly technical and internationally recognised meanings and most of these are included in the Demand Reduction Glossary of Terms (United Nations International Drug Control Program (UNDCP) 2000). These definitions and terms, in addition to those drawn from other international glossaries, are attached in Appendix 3 of this Interim Report. It is essential, however, that two of the key terms that form the subject matter of this Inquiry – *abuse* and *misuse* of pharmaceutical drugs – are clearly defined at the outset.

Drug abuse has been stated to be 'A term in wide use but of varying meaning' (United Nations International Drug Control Program 2000, p.1). In international drug control conventions, '"Abuse" refers to any consumption of a controlled substance no matter how infrequent'. The American Psychiatric Association's Diagnostic and Statistical Manual (DSM) of Mental Disorders, defining abuse in the context of psychoactive substances, states that it will usually result in 'a maladaptive pattern of substance use leading to clinically significant impairment or distress' (DSM-IV American Psychiatric Association 1994 cited in United Nations International Drug Control Program 2000, p.1). The way in which such maladaptive behaviour is manifested giving rise to a pattern of drug abuse is expanded in the definition contained in the glossary in Appendix 3 of this Interim Report.

Drug misuse, on the other hand, is usually characterised in the sense that a drug, usually a licit drug, is not used appropriately or for the purposes for which it was developed. The UNDCP Glossary defines misuse as: 'The use of a substance for a purpose not consistent with legal or medical guidelines, as in the non medical use of prescription medications. The term is preferred by some to abuse in the belief that it is less judgemental' (UNDCP 2000, p.45).

Overview of the Interim Report

As indicated in the introduction to this chapter, the misuse of benzodiazepines and other forms of pharmaceutical drugs result in a wide range of harms. Current and potential responses are made more challenging by the need to consider the legitimate and beneficial use of these medications when safely and appropriately prescribed. Effective responses to the misuse of these drugs will consider both the intended and legitimate use of the medicines as well as the specific adverse harms that can arise from their misuse. It will be important to review the legislative framework at a national and local level and explore the related regulations and guidelines that govern the safe and effective prescription and supply of these drugs by medical practitioners and pharmacists. Even with the most effective systems of regulation and control, and the highest quality

practice, there is the risk that some individuals will misuse and experience harm from benzodiazepines and other pharmaceuticals. It is important that information, education, harm reduction and treatment strategies are developed alongside legislative/regulatory and professional practice responses.

The substantive part of this Interim Report commences (Chapter 2) with a brief description of the nature of the medicines being considered by this Inquiry, focussing on their intended uses in treatment and their effects – in short, why they are prescribed. The following chapter (Chapter 3) examines the extent of their legitimate use and presents evidence regarding the extent of misuse, at an international, national and local level. Chapter 4 focuses on the potential adverse consequences of these medications, especially when they are misused. Having established the consequences of use, Chapter 5 explores the factors and contexts that contribute to unlawful access to and misuse of these medicines – that is, why individuals engage in misuse of pharmaceutical medicines and how they acquire them.

Chapters 6 and 7 examine the legislative and regulatory frameworks that guide access to clinically prescribed medications and aim to reduce the risky use and misuse. Chapter 7 also reviews the various roles of key professional and statutory groups and highlights the critical importance of quality information and monitoring systems.

Chapters 8 and 9 explore the various education, harm reduction and treatment options that can help reduce pharmaceutical misuse and related harms, at both a community and an individual level.

The final chapter, Chapter 10, summarises the Interim Report, identifying key areas for future review.

2. The Therapeutic Use of Benzodiazepines and Other Forms of Pharmaceutical Drugs

This chapter presents information about the effects of therapeutic use of benzodiazepines and narcotic analgesic drugs. It is not intended to be an exhaustive review. Rather, the chapter aims to provide an overview of the effects and treatment uses of these medications. The chapter is presented in three sections covering the benzodiazepines, the opioid analgesics and the opioids used in the management of opiate dependency.

Benzodiazepines

Benzodiazepines are a class of drug commonly used as sedative/hypnotics (drugs to assist relaxation and sleep) and anxiolytics (drugs to relieve anxiety). They are also used in anaesthesia and in epilepsy medication.

> Some benzodiazepines are prescribed by doctors to relieve stress and anxiety and to help people sleep. They are also used to treat epilepsy (sometimes), to relax muscles, to help people withdraw from alcohol, or as an anaesthetic before surgery.[13]

When they were first introduced (in the 1960s) they were seen as a valuable alternative to the barbiturates, which had been used for similar purposes but were associated with dependence and implicated in cases of intentional and unintentional overdose (Richards 2005). It was found that restriction of the availability of barbiturates in the early 1970s reduced deaths due to suicide as a result of barbiturate overdose. This was at a time when benzodiazepines were introduced as an alternative drug for the treatment of insomnia (Oliver & Hetzel 1972).

The efficacy of benzodiazepines as compared to barbiturates was explained to the Committee by Susan Alexander of the pharmaceutical company Roche Australia:

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13 The Australian Drug Foundation (ADF) website (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=benzodiazepines).

> Benzodiazepines as a class commenced with the Roche discovery of chlordiazepoxide (Librium) in 1957....The benzodiazepines have come to play an essential role in modern clinical practice, not only in the treatment of sleep and anxiety disorders but in a wide variety of psychiatric and medical uses. Benzodiazepines are considered to be remarkably safe compared to other medicines used for these indications. As a class, they are safer than the family of drugs that they have largely replaced, which is the barbiturates, and are considered one of the safest options available today for the medical treatment of these disorders.[14]

Dr Mike McDonough also expanded on the background to the development of benzodiazepines:

> Pre the 1960s what the medical profession was prescribing here, in the US and in Europe as tranquillisers and sleeping tablets were drugs known as the bromides, the barbiturates and chloral hydrate…from a public health perspective, one would have to reflect on the greater and significant mortality – that is, overdose mortality – [resulting from these drugs]. Most of the movie stars that died from overdose…took barbiturates. Marilyn Monroe for example, was thought to have taken barbiturates…[15]

Benzodiazepines, when first introduced on the market, were conversely viewed as a much safer drug:

> Since the fifties there has been a dramatic decline in 'tranquilliser' overdose mortality, and since the increased availability of benzodiazepines there has been a dramatic decline in overdose death. Most overdose cases that present to our hospitals now are able to be discharged within 24 hours. They do not generally have a fatal outcome. There surely are some (still 'too many') but the overwhelming majority are non-lethal and the overwhelming majority present as cases that we in the hospitals call 'cocktails', because there is often alcohol with some benzodiazepines.[16]

Apart from a reduction in death by overdose, suicide or misadventure, it was initially also thought that the benzodiazepines were free of 'addictive' properties, but by the 1970s it had become clear that these drugs could produce

14 Ms Susan Alexander, Head of Regulatory Affairs and Head of Operations, Roche Products on behalf of Medicines Australia, in conversation with the Drugs and Crime Prevention Committee (via telephone), 20 June 2006. It should be noted that Ms Alexander was speaking primarily in her role as a representative of Medicines Australia, the peak industry body for pharmaceutical companies in Australia.

15 Dr Mike McDonough, Medical Director Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 20 June 2006.

16 Dr Mike McDonough, Medical Director Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 20 June 2006.

withdrawal symptoms consistent with the development of dependence (de la Cuevas et al. 2003).[17]

Since their introduction, the benzodiazepines have become one of the most widely used groups of medications around the world, second only to drugs prescribed for heart and circulatory problems (World Health Organization (WHO) 1996). General practitioners prescribe around 80 per cent of all benzodiazepines, and an average of 10 per cent of the world's population use benzodiazepines as tranquillisers or hypnotics (WHO 1996). In Australia and New Zealand it is estimated that around 4 per cent of all prescriptions from general practitioners are for the benzodiazepines (Hulse, White & Cape 2002).[18]

In Australia there are currently 11 widely used benzodiazepine formulations. Table 2.1 describes the many common benzodiazepines and their brand names, the scheduling of the drugs,[19] the form in which they are available (tablet, capsule etc.) and the purpose of the prescription/treatment (the indication).

Table 2.1: Benzodiazepines frequently used in Australia – active ingredient, brand name, company, schedule, indications, form and access

Drug Name	Proprietary Name	Company	Schedule	Indication	Form	Restricted
alprazolam	Alprax	Arrow	S4	Anxiety including anxious patients with some symptoms of depression (short-term); panic disorder	T	yes[a]
	Alprazolam-DP	Douglas Pharmaceuticals	S4	Anxiety including anxious patients with some symptoms of depression (short-term); panic disorder	T	yes[a]
	Zamhexal	Hexal Aust	S4	Anxiety including anxious patients with symptoms of depression (short-term); panic disorder	T	yes[a]
	Xanax	Pharmacia	S4	Anxiety including anxious patients with symptoms of depression (short-term); panic disorder	T	yes[a]
	Kalma	Alphapharm	S4	Anxiety including anxious patients with some symptoms of depression (short-term); panic disorder	T	yes[a]
	Chem Mart	GenRx	S4	Not stated	T	yes[a]
bromazepam	Lexotan	Roche	S4	Tension, anxiety, agitation	T	Yes[b]

cont'd over…

17 Problems of dependence are discussed in Chapter 3. Also, see Appendix 3 for a definition of dependence.

18 Chapter 4 describes in detail the rates of use and misuse of benzodiazepines.

19 Pharmaceutical drugs are scheduled from S2 to S9. This affects their availability (eg. lower schedule drugs are more easily available, higher schedule drugs are more strictly controlled). See Chapters 6 and 7 for a detailed explanation.

Drug Name	Proprietary Name	Company	Schedule	Indication	Form	Restricted
clobazam	Frisium	Aventis	S4	Acute anxiety and sleep disturbances associate with anxiety	T	No
clonazepam	Rivotril	Roche	S4	Partial and generalised epilepsy in adults and children; Status epileptius	T, L, I	Yes[c,d,e,f,g]
	Paxam	Alphapharm	S4	Partial and generalised epilepsy in adults and children	T	Yes[c,d,e]
diazepam	Antenex	Alphapharm	S4	Anxiety disorders or short-term relief of anxiety; acute alcohol withdrawal; muscle spasm	T	For more than 50x2mg tablets [h,i]
	Valpam	Arrow	S4	Anxiety disorders or short-term relief of anxiety; acute alcohol withdrawal; muscle spasm; spasticity	T	For more than 50x2mg tablets [h,i]
	Valium	Roche	S4	Anxiety disorders or short-term relief of anxiety; acute alcohol withdrawal; muscle spasm; spasticity; status epilepticus, tetanus	T, I	For more than 50x2mg tablets [h,i]
	GenRx Diazepam	GenRx	S4	Anxiety disorders or short-term relief of anxiety; acute alcohol withdrawal; muscle spasm; spasticity in cerebral palsy; paraplegia; athetosis; stiff man syndrome	T	No
	Ducene	Sauter Laboratories	S4	Anxiety disorders or short-term relief of symptoms of anxiety; acute alcohol withdrawal; muscle spasm	T	Yes [h,i]
	Diazepam-DP	Douglas Pharmaceuticals	S4	Management, short-term relief of anxiety disorders; acute alcohol withdrawal; muscle spasm	T	Yes [h,i]
	Diazepam Injection (DBL)	Mayne Pharma	S4	Anxiety disorders or short-term relief of anxiety; acute alcohol withdrawal; muscle spasm; spasticity in cerebral palsy; paraplegia; athetosis; stiff man syndrome; pre-op medication	I	No
	Diazepam Elixir (10mg/10ml)	Orion Laboratories	S4	Anxiety; muscle spasm; cerebral spasticity; acute alcohol withdrawal	L	No
flunitrazepam	Hypnodorm	Alphapharm	S8	Severe insomnia	T	Yes
lorazepam	Ativan	Sigma Pharmaceuticals	S4	Anxiety disorders or short-term relief of symptoms; anxiety associated with depressive symptoms, pre-op medication	T	No

Drug Name	Proprietary Name	Company	Schedule	Indication	Form	Restricted
midazolam	Hypnovel	Roche	S4	Short-acting sleep inducing agent for conscious sedation for short procedures and the induction of anaesthesia; sedation in ICU; pre-op medication	I	No
	Midalzolam Injection and Midazolam injection BP Midazolam Sandoz	Pfizer Mayne Pharma Sandoz	S4 S4 S4	Short-acting sleep inducing agent for conscious sedation for short procedures and the induction of anaesthesia; sedation in ICU; pre-op medication	I	No
nitrazepam	Mogadon	Valeant	S4	Insomnia	T	Yes [j,k]
	Alodorm	Alphapharm	S4	Insomnia	T	Yes [j,k]
oxazepam	Serepax	Sigma	S4	Anxiety disorders or short-term relief of symptoms; anxiety associated with depressive symptoms; alcohol withdrawal	T	Yes [j,k]
	Murelax	Fawns & McAllen	S4	Anxiety disorders or short-term relief of symptoms; anxiety associated with depressive symptoms; alcohol withdrawal	T	Yes [j,k]
	Alepam	Alphapharm	S4	Anxiety disorders or short-term relief of symptoms; anxiety associated with depressive symptoms; alcohol withdrawal	T	Yes [j,k]
temazepam	Normison	Sigma	S4	Adjunctive therapy in the short-term management of insomnia in adults	T	Yes [l,m]
	Temaze	Alphapharm	S4	Adjunctive therapy in the short-term management of insomnia in adults	T	Yes [l,m]
	Temtabs	Fawns & McAllen	S4	Adjunctive therapy in the short-term management of insomnia in adults	T	Yes [l,m,n]
triazolam	Halcion	Pfizer	S4	Short-acting hypnotic, insomnia (short-term treatment	T	No
flunitrazepam	Hypnodorm	Alphapharm	S8	Severe insomnia	T	Yes [o,p]

Notes:

1. Indication for authority for restricted use: a) panic disorder where other treatments have failed or are inappropriate; b) Patients with terminal illness; refractory phobic or anxiety states; c) Tablets-continuing supply for palliative care patients for the prevention of epilepsy; d) continuing supply for palliative care patients for the prevention of epilepsy where consultation with a specialist has occurred; e) neurologically proven epilepsy; f) liquid-neurologically proven epilepsy; g) injection- continuing supply for palliative care patients for the prevention of epilepsy; h) continuing supply for palliative care where anxiety is a problem; i) continuing supply for palliative care where anxiety is a problem where consultation with a specialist has occurred; j) continuing supply for palliative care where anxiety is a problem; k) continuing supply for palliative care where anxiety is a problem where consultation with a specialist has occurred; l) malignant neoplasia; m) continuing supply for palliative care where insomnia is a problem; n) continuing supply for palliative care where insomnia is a problem where consultation with a specialist has occurred; o) Patients with terminal disease; p) Patients with refractory phobic or anxiety states
2. Key for 'Form': T – Tablet L – liquid, oral solution I – injection

Source: MIMS Online 2003.

The effects of benzodiazepines

Benzodiazepines depress the activity of the central nervous system and slow down the messages travelling to and from the brain. They affect physical, mental and emotional responses. Some effects are the intended therapeutic effects (for example, reduced anxiety) and others are unwanted side effects. Both intended and side effects can be divided into short-term effects and long-term effects, and have been summarised by the Australian Drug Foundation (ADF) as follows:

Immediate effects

Low to moderate doses

Short-term use (less than two weeks) of benzodiazepines may have the following effects: relaxation; calmness; relief from tension and anxiety.

Other effects can include drowsiness, tiredness, lethargy, dizziness, vertigo, blurred or double vision, slurred speech, stuttering, mild impairment of thought processes and memory, feelings of isolation and emotional depression.

Higher doses

The most probable effects of higher doses are: drowsiness; over-sedation; sleep.

Before the person falls asleep, or if they do not sleep, higher doses may produce an effect similar to alcohol intoxication. Effects could be confused, slurred speech, poor coordination, impaired judgement, difficulty thinking clearly, loss of memory, blurred or double vision and/or dizziness. Mood swings and aggressive outbursts may also occur. The symptoms intensify as the dose increases. Feelings of jitteriness and excitability often become evident as the effects of large doses wear off.

Overdose

Very high doses of benzodiazepines can cause unconsciousness or coma. Death rarely occurs from overdose of benzodiazepines alone, but some deaths have occurred when large doses were combined with alcohol or other drugs. Deaths have occurred due to the inhalation of mucus or vomit while the person has been unconscious.

Long-term effects

The use of benzodiazepines over a long period of time (more than two to three weeks) is not recommended.

Benzodiazepines can help to relieve anxiety in the short term. However, they do not solve the problem that caused the anxiety in the first place – they treat the symptoms but not the cause.

Long-term use of benzodiazepines may cause: drowsiness; lack of motivation; difficulty thinking clearly; memory loss; personality change; changes in emotional responses; anxiety; irritability; aggression; difficulty sleeping; disturbing dreams; nausea; headaches; skin rash; menstrual problems; sexual problems; greater appetite; weight gain; increased risk of accidents; increased risk of falling over (older people).

> Very high doses of benzodiazepines over a long period of time may cause confusion, lack of coordination, depression and slurred speech, and may lead to increased aggressiveness.
>
> It is ironic that the long-term effects include anxiety and sleeplessness, when these are the very problems that benzodiazepines are supposed to relieve.[20]

The half-life of benzodiazepines

Among other factors, the choice of which drug is prescribed for a particular condition is affected by how quickly they take effect and how long they last.[21] This is related to their half-life, described as follows:

> The term [half-life] refers to the time needed for the blood level of a particular drug to decline to half of the maximum level (peak). After absorption, the various drugs are transported to the various sites of action through the blood stream. During this transportation and distribution process, the drugs already in the blood or in the various organs are gradually transformed into various metabolites, and either deposited or excreted from the body…Half-life is a generally accepted…indication of the relative duration of a drug's effects. Heroin, for example, has a short half-life, while morphine has a longer one. The various benzodiazepines and barbiturates also have greatly varying half-lives (United Nations Office for Drug Control and Crime Prevention (UNODCCP 2000, p.30).[22]

The 'half-life' of a drug is important because it has implications for the duration of drug effects and, if a person becomes dependent, for withdrawal management.[23] Thus, different benzodiazepines will be prescribed for different purposes. The WHO (1996) classifies benzodiazepines into three broad groups according to their elimination half-life:

- Long-acting benzodiazepines have half-lives which generally exceed 24 hours;
- Intermediate and short-acting benzodiazepines have half-lives which range from five to 25 hours; and
- Ultra short-acting benzodiazepines have half-life values of less than five hours.

Speed of onset of drug effect and abuse liability

There is good evidence that the reinforcing effects of drugs, and the likelihood that their use will lead to drug dependence and addiction, or be sought for abuse, depends on the speed at which the drug enters the brain and causes an effect, and how quickly the drug is removed. This is determined by the

20 ADF website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=benzodiazepines).

21 ADF website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=benzodiazepines).

22 See Appendix 3 for a fuller definition.

23 See Chapter 9 for a discussion in the context of treatment and Appendix 3 for a definition of 'half-life'.

pharmacokinetics (absorption, metabolism, distribution and elimination) of the drug. In addition, solubility in lipids (lipophilicity) is also important, because drugs soluble in lipids cross the barrier between the blood stream and the brain (the blood-brain barrier) more rapidly. Drug formulations or routes of administration (such as intravenous injection or snorting) that enable rapid entry of the drug into the brain increase the potential for addiction and dependence (Gossop et al. 1992).

Early evidence suggests that rapid-acting and short-lived barbiturates had greater abuse potential than slower onset long-acting barbiturates (Jaffe 1990). Additionally, researchers have found that rapidly administered drugs tend to be those that produce subjective pleasurable effects (Abreu et al. 2001). Much of the research on speed of onset and its effects on abuse liability has been done on the benzodiazepine drugs. Research comparing slower onset benzodiazepines with more rapid onset benzodiazepines suggests that the former have substantially lower abuse potential (Griffiths et al. 1984; Busto & Sellers 1986). Another study suggested that the subjective effects produced by diazepam were greater than those produced by oxazepam, a difference attributed to the greater lipid solubility of diazepam, a difference that would contribute to a more rapid onset of effect (Bliding 1974). In addition, a rapid decrease in drug concentration is associated with a termination of the 'high' and a resumption of drug-seeking behaviour (O'Brien CP 2001).

Side effects

As already indicated, there are some side effects, or unwanted effects to the use of benzodiazepines. One of the most common short-term adverse effects of benzodiazepines is drowsiness, which occurs in 10 to 15 per cent of those taking therapeutic doses, although this common side effect usually diminishes after a few days of treatment (due to the development of tolerance) (Barker et al. 2003). This consequence of drowsiness clearly has repercussions for driving impairment, an issue discussed further in Chapter 4. Most of the acute side effects of the benzodiazepines, however, are related to the central nervous system effect of the drug and include fatigue, ataxia (difficulty in coordinating movement), confusion and weakness.

The use of benzodiazepines in the elderly may be a risk factor for falls, hip fracture, and cognitive impairment. Long-acting benzodiazepines may be associated with a higher risk than short-acting benzodiazepines (Ray, Thapa & Gideon 2000). Also, studies in patients and healthy volunteers have shown that benzodiazepines impair anterograde memory (memory from the time the drug is taken, and for the period when there are sufficient levels detectable in the blood) in a dose-dependent manner, without affecting long-term memory (Taylor & Tinklenberg 1987). Table 2.2 below lists the reported side effects of benzodiazepines.

Table 2.2: Side effects associated with benzodiazepines

Side effects		
Aggression	Agitation	Anorexia
Anterograde amnesia	Auditory hallucinations	Bitter or metallic taste
Bizarre behaviour	Constipation	Delirium
Depression	Dry mouth	Dysathria (slurred speech, difficulty pronouncing words)
Failure to ovulate	Falls in the elderly	Flushing
Gastro-intestinal complaints	Genitor-urinary complaints	Headache
Hiccups	Increased or decreased libido	Increased appetite
Increased salivation	Joint pain	Menstrual irregularities
Muscle cramps	Nausea	Palpitations
Panic	Paranoid ideation	Shortness of breath
Swollen tongue	Tachycardia	Visual disturbances
Vivid dreams	Weight loss	

Source: Adapted from Barker et al. 2003, p.204.

Most side effects are dose-dependent – the higher the dose the higher the risk of side effects. Such side effects may be more likely to occur among the elderly who are more susceptible, due to factors such as an impaired ability to metabolise and excrete a drug (WHO 1996; Longo & Johnson 2000).

There are also some long-term consequences, although these cannot be identified with as much confidence because there are various methodological difficulties in the studies (Barker et al. 2003; Curran 1991 cited in Barker et al. 2003). One common and problematic long-term effect of benzodiazepine use is dependence. This can occur even at therapeutic doses, a risk that has prompted the following prescribing information and advice from MIMS Online:

> In general, benzodiazepines should be prescribed for short periods only (e.g two to four weeks). Continuous long-term use is not recommended. There is evidence that tolerance develops to the sedative side effects of benzodiazepines. After as little as one week of therapy, withdrawal symptoms can appear following the cessation of recommended doses (MIMS Online 2003).

Thus, even with therapeutic doses, tolerance and dependence can develop reasonably quickly and some people can become dependent within a few days.

> …the thing to remember is that these medications are usually prescribed on what is believed to be a short-term basis. They almost invariably are started for sleeping difficulties that present around a particular issue, whether that be a grief issue or an illness that is considered to be time limited. Often the problem then becomes that, after a week or so of using the medications, it can be quite hard to stop them. Then the cycle of dependence can begin. I think there are two issues there: are they being prescribed in the recommended way for limited

> periods of time and are other issues being looked at, which I think is quite difficult in a community medical setting where there is a lot of time pressure.
>
> …Most people would become dependent after two weeks – within that period – but most people would have some degree of dependence after a week. In hospital, we use these medications sometimes for alcohol withdrawal, and we are very careful to make sure people are not on them for more than five days because after five days we have to bring down the doses very slowly, rather than just stopping them – so dependence develops very quickly.[24]
>
> ...Different ones come on quickly and wear off quickly so we have found that with the ones that come on and wear off quickly such as alprazolam or Xanax the severity of dependence seems to come on a bit quicker and a bit more. So the ones that dribble out of your system slowly do not seem to be as nasty when you cease them suddenly. Alprazolam, for example, because it goes away quickly, people tend to very quickly start to get very agitated and even occasionally have seizures. But generally, yes, about a week; they cause dependence quite quickly.[25]

Finally, as already indicated, benzodiazepines are depressant drugs (in terms of their action on the central nervous system). In combination with other depressant drugs, the effects of both can be exacerbated:

> Combining benzodiazepines with alcohol, barbiturates, antihistamines, antidepressants, cannabis, or heroin can greatly increase the effects of the drugs taken. This can be very dangerous, especially if the person intends to drive. Some combinations can be life threatening.
>
> Taking benzodiazepines with alcohol greatly reduces alertness and judgment of time, space, and distance. When large amounts of alcohol and benzodiazepines are taken together, it can result in death.
>
> Combining benzodiazepines with other sedatives, antihistamines (cough, cold and allergy remedies), barbiturates or sleeping pills increases the effects on the brain, resulting in unconsciousness and failure to breathe, which can lead to death.
>
> The combination of heroin and benzodiazepines can be deadly. With benzodiazepines in the system, it takes less heroin to overdose.[26]

These adverse consequences are addressed in more detail in Chapter 4.

In summary, benzodiazepines are widely used in treatment for a range of medical conditions and can be effective therapies. For example, Ms Susan Alexander, a representative of the pharmaceutical industry in Australia, has stated:

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24 Dependence is further discussed in Chapter 3 and, in relation to treatment, in Chapter 9. Also, see Appendix 3 for a definition of dependence.

25 Dr Matthew Frei, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

26 ADF website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=benzodiazepines).

> From the Roche position, preclinical, clinical and epidemiological studies have demonstrated that benzodiazepines have a relatively low potential for abuse. There is little evidence that patients prescribed them for legitimate reasons abuse them. There is a great body of evidence to show that benzodiazepines are abused by those already misusing and abusing other largely illegal drugs. There is little compelling evidence to show that different benzodiazepines differ in abuse potential. Roche has sponsored numerous epidemiology studies to better establish the nature of benzodiazepine use and abuse in the US, the Netherlands, Germany and France. National studies of drug abuse show that polydrug addicts may use benzodiazepines to help overcome the withdrawal symptoms of heroin addiction, which is nervousness and sleep problems, and to dampen the depressive effects of cocaine addiction.[27]

Whatever disagreement there may be with regard to the exact extent of benefits or harms attributable to their ingestion, it is undoubtedly true that in most circumstances the use of benzodiazepines is an improvement upon the barbiturate drugs of an earlier period.

However, as the above discussion has indicated, there are also various side effects, some of which can be quite unpleasant. Side effects are influenced by dose and individual characteristics. In addition, both the short- and long-term effects of benzodiazepine use can have serious consequences. Tolerance and dependence to benzodiazepines can occur quickly and the drug effects, and negative consequences, can be exacerbated if combined with other central nervous system depressants.

Narcotic analgesics (opioids)

'Opioid' is a general term which includes drugs containing natural opiates derived from the opium poppy and a range of synthetic and semi-synthetic substances which have morphine-like effects. Opioids, or narcotic analgesics, are commonly:

> …taken to relieve pain, the most common complaint that physicians hear from their patients. Opioids are prescribed for three types of pain: acute or short-lived pain, chronic malignant (cancer) pain and chronic non-malignant pain…Opioids attach to opioid receptors in the brain, block the transmission of pain signals to the brain and, like illicit opioids (e.g. heroin), produce a sense of heightened pleasure. The use of opioids is an important component of pain management (National Center on Addiction and Substance Abuse 2005, p.13).

Opioid use has a long history, as the following quote from the National Centre for Epidemiology and Population Health reveals:

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27 Ms Susan Alexander, Head of Regulatory Affairs and Head of Operations, Roche Products on behalf of Medicines Australia, in conversation with the Drugs and Crime Prevention Committee (via telephone), 20 June 2006. It should be noted that Ms Alexander was speaking primarily in her role as a representative of Medicines Australia, the peak industry body for pharmaceutical companies in Australia.

> The opioids have been used both medically and recreationally for centuries. A tincture of opium called laudanum has been widely used since the 16th century as a remedy for 'nerves' or to depress coughing or stop diarrhoea. By the early 19th century, morphine had been extracted in a pure form suitable for solutions, and with the introduction of the hypodermic needle in the mid-19th century, injection of the solution became the common method of administration. Heroin (diacetylmorphine) was first marketed in 1898 for general medical use and was heralded firstly as a cough suppressant, then in 1900 as a remedy for morphine addiction. Of the 20 alkaloids contained in opium, only codeine and morphine are still in widespread clinical use today. In this century, many synthetic drugs have been developed which have essentially the same effects as the natural opium alkaloids.
>
> The opioid-related synthetic drugs, such as pethidine and methadone, were developed to provide an analgesic without dependence-producing properties. Unfortunately, however, all the opioids and their synthetic derivatives which are effective as analgesics are also dependence producing. Modern research has led to the development of another family of drugs called narcotic antagonists (eg naloxone hydrochloride). These drugs are not used as painkillers, but to reverse the effects of opioid overdose.[28]

The effects of opioids are influenced by how much is used, how it is ingested and individual factors.

Immediate effects

The immediate effects of opioids relate to analgesia (relief of pain) and euphoria (a feeling of wellbeing). The latter effect may also be directly associated with the analgesic effect. Other short-term and immediate consequences as described by the National Centre for Epidemiology and Population Health include:

> Production of nausea and vomiting. Depression of respiration – the cause of death from overdose. Reduction of movements of the bowel (intensive constipation). Miosis (constriction of the pupils of the eyes).
>
> The main therapeutic application of the narcotics is for the relief of severe pain. The drug effect is not on the perception of pain but rather upon its interpretation by the brain. Typically, the patient is aware that the pain is still present, but it is no longer interpreted as being painful or disturbing. The euphoric and dependence-producing capacity of these drugs is probably directly associated with this action. Other therapeutic applications are for cough suppression and treatment of diarrhoea. Synthetic and semi-synthetic derivatives have been made and selected for their specificity for these actions with a minimum of dependence producing capability.

28 National Centre for Epidemiology and Population Health, Australian National University, cited from http://nceph.anu.edu.au/Publications/Opioids/stage1vol2b.pdf.

> Narcotics briefly stimulate the higher centres of the brain, then depress the activity of the central nervous system. Immediately after injection the user feels a surge of pleasure ('a rush') which gives way to a state of gratification into which hunger, pain and sexual urges usually do not intrude. The dose required to produce this effect may initially cause restlessness, nausea and vomiting. The effects of a usual dose in a therapeutic setting lasts approximately 3 to 4 hours.
>
> With moderately high doses the body feels warm, the extremities heavy and the mouth dry. The user goes 'on the nod', an alternately wakeful and drowsy state during which the world is forgotten. As the dose is increased, breathing becomes progressively more depressed. With very large doses the person cannot be roused, the pupils are contracted to pinpoints, the skin is cold, moist and bluish, and profound respiratory depression resulting in death may occur.[29]

Effects of prolonged use

The major longer-term hazards associated with opioid analgesics are respiratory depression and, to a lesser degree, circulatory depression. There are, however, a wide range of common and uncommon side effects associated with opioids affecting the cardiovascular system, the nervous system, the skin, the gastro-intestinal tract, the excretory system, the liver and gall bladder and the endocrine system. In normal doses, the most common side effects of opioid analgesics are nausea, vomiting, constipation, drowsiness and confusion. Larger doses produce respiratory depression and hypotension with circulatory failure and deepening coma (MIMS Online 2003).

The amount required to produce life threatening respiratory depression varies considerably with the individual and regular users may tolerate large doses. In long-term use, physical dependence and tolerance may develop. Commenting on the dangers associated with long-term use of analgesic opioids, the National Centre for Epidemiology and Population Health states:

> The narcotic analgesics, in pure form and administered cleanly, are non-toxic to body tissue. If not administered cleanly in pure form, chronic opioid users may develop endocarditis, an infection of the heart lining and valves by organisms introduced into the body during injection of the drug…The main problem associated with the prolonged usage of narcotics is the development of tolerance and a withdrawal syndrome. In the therapeutic situation, these problems can be avoided or minimised by carefully regulating the interval between doses.[30]

The following withdrawal symptoms may be observed after narcotics are discontinued: body aches, diarrhoea, gooseflesh, loss of appetite, nervousness, restlessness, runny nose, sneezing, tremors or shivering, stomach cramps,

29 National Centre for Epidemiology and Population Health, Australian National University, cited from http://nceph.anu.edu.au/Publications/Opioids/stage1vol2b.pdf.

30 National Centre for Epidemiology and Population Health, Australian National University, cited from http://nceph.anu.edu.au/Publications/Opioids/stage1vol2b.pdf.

nausea, trouble with sleeping, unusual increase in sweating and yawning, weakness, tachycardia and unexplained fever. With appropriate medical use of narcotics and gradual withdrawal from the drug these symptoms are usually mild (MIMS Online 2003).

Table 2.3 indicates many of the opioid drugs available on prescription in Australia.[31] This table provides information on their common name, the major therapeutic purpose for each drug and the form in which it is prescribed.

Table 2.3: Narcotic analgesics used in Australia – active ingredient, brand name, company, schedule, indications, form and access

Drug Name	Proprietary Name	Company	Schedule	Indication	Form	Restricted
Morphine HCl	Ordine	Mundipharma	S8	severe pain	I, T, L	yes[b]
	RA Morph	Pfizer	S8	opioid analesic	L	yes[b]
	M.O.S.	Valeant	S8	opioid analgesic	L	yes[b]
	MS Mono	Mundipharma	S8	chronic severe pain	C	yes[a]
Morphine Tartrate	Morphine Tartrate (inj)	Mayne	S8	severe intractable pain in cancer patients	I	yes[a]
Morphine Sulphate	Kapanol	GlaxoSmithKline	S8	chronic pain unresponsive to non-narcotic analgesia	C	yes[b]
	Anamorph	Fawns & McAllen	S8	chronic severe pain of cancer	T	yes[b]
	MS Mono	Mundipharma	S8	severe pain with inadequate response to other measures		
	MS Injection	Mayne	S8	moderate to severe pain unresponsive to non-opioids, pre-operative medication, analgesic adjunct in general anaesthestic	I	no
	Sevredol	Mundipharma	S8	chronic severe pain of cancer	T	yes[b]
Oxycodone HCl	Oxycontin	Mundipharma	S8	moderate to severe pain unresponsive to non-opioids, pre-operative medication, analgesic adjunct in general anaesthestic	T (CR)	yes[a]
	Oxynorm	Mundipharma	S8	moderate to severe pain	C, L	yes[b]
	MS Contin	Mundipharma	S8	opioid responsive, chronic severe pain	CRT, CRS	yes[a]
	Endone	Sigma	S8	moderate to severe pain	T	yes[b]
Oxycodone pectinate	Prolodone	Pharmalab	S8	pain, especially post-op and in carcinoma	S	yes[b]
Hydromorphone	Dilaudid	Abbott	S8	opioid analgesia, moderate to severe pain	T, L, I	yes[b]

31 MIMS Online 2003.

Drug Name	Proprietary Name	Company	Schedule	Indication	Form	Restricted
Fentanyl	Durogesic	Janssen-Cilaq	S8	opioid analgesic, management of chronic pain	P	yes[a]
	Fentanyl injection DBL	Mayne Pharama	S8	analgesia in anaesthesia and peri-operatively, with a neuroleptic, anaesthesia induction, maintenance	I	no
	Fentanyl	AstraZeneca	S8	analgesia in anaesthesia	I	no
Dextro-propoxyphene napsylate	Doloxone	Aspen Pharmacare	S4	mild to moderate pain	T	no
Oripavine derivative	Norspan	Mundipharma	S8	moderate to severe pain	P	yes[a]
Pethidine	Pethidine Injection	Mayne Pharma	S8	moderate to severe pain (short-term) anaesthetic adjunct, obstertric analgesia	I	no
	Pethidine hydrochloride	Sigma	S8	moderate to severe pain, pre-op medication, analgesia adjunct in general anaesthetic, obstetrics	I	no
	Pethidine Injection BP	AstraZeneca	S8	moderate to severe pain, pre-op medication, analgesia adjunct in general anaesthetic, obstetrics	I	no
Methadone HCl	Physeptone	GlaxoSmithKline	S8	pain, treatment of opiate dependence	I, T	yes[c]
	Biodone Forte	National Sales	S8	treatment of opiate dependence	L	yes[c]
	Methadone Syrup	GlaxoSmithKline	S8	treatment of opiate dependence	L	yes[c]
Buprenorphine	Subutex	Reckitt Benckiser	S8	opiate dependence (maintenance and detoxification)	SLT	yes[c]
	Temgesic	Reckitt Benckiser	S8	opioid agonist; acute, moderate to severe pain (short-term use less than or equal to 1 week)	I, SLT	no
	Norspan	Mundipharma	S8	moderate to severe pain	P	no
Buprenorphine and naloxone	Suboxone	Reckitt Benckiser	S8	opiate dependence in conjunction with medical, social and psychological treatment	SLT	yes[c]

Notes:

1. Indication for restricted use: a) chronic severe disabling pain not responding to non-narcotic analgesic; b) severe disabling pain not responding to non-narcotic analgesics; c) opioid management
2. T -Tablet L – liquid, oral solution I – injection C – capsule
   P – patch SLT – sublingual tablet S – suppository CRT-controlled release tablet
   CRS-controlled release suspension.

Source: MIMS Online 2003.

As indicated in Table 2.3, there is a range of different narcotic analgesic drugs, some of which are discussed briefly in the list below. Most are S8 drugs (prescription only, with strict controls) but some are more widely available.[32]

32 There are various schedules for drugs. This affects their availability (eg. lower schedule drugs are more easily available, higher schedule drugs are more strictly controlled). See Chapters 6 and 7 for a detailed explanation.

The following information is drawn from that published in MIMS Online (2003) medicine database.[33]

- **Morphine:** Morphine is derived from opium. It affects the central nervous system and smooth muscle. The analgesia induced by morphine is a result of increases in both the pain threshold and pain tolerance: patients remain aware of the existence of the pain but are less distressed by it. Morphine relieves most types of pain but is more effective against dull constant pain and is recommended for use in the chronic severe pain of cancer. Morphine drugs used in Australia include Sevredol®, Anamorph®, Kapanol®, MS Contin® and MS Mono®.
- **Hydromorphone:** Hydromorphone is derived from morphine but is approximately eight times more potent. It is used for moderate to severe pain. It is available as a tablet, oral liquid and in solution for injection. A high potency injection for use in opioid dependent patients is also available. In Australia, hydromorphone is available as Dilaudid®.
- **Fentanyl:** Fentanyl is a synthetic opioid analgesic. It has similar properties to morphine. It differs from morphine in that it has a rapid onset and short duration of action. It is used as a short acting analgesic during periods of anaesthesia, as a pre-operative medication, and as an analgesic immediately following surgery. In Australia, fentanyl is available as: Actiq® (in the form of a lozenge); as Sublimaze®, and Fentanyl® injections for post-operative use; Durogesic® as a transdermal patch; and Naropin® with fentanyl as an epidural infusion. Actiq® is a high potency fentanyl preparation only for use with patients who have developed a tolerance to other opioid analgesia and are experiencing breakthrough pain.[34]
- **Pethidine:** Pethidine is a synthetic opioid analgesic with actions similar to those of morphine. It is primarily used as an analgesic, as a pre-operative medication, as an obstetric analgesic and as an adjunct in anaesthesia. Prolonged use of pethidine is associated with a number of severe side effects (it is neurotoxic) and use is not recommended for periods longer than 24 to 36 hours.
- **Oxycodone:** Oxycodone is a semi-synthetic narcotic analgesic available in Australia as Endone®, Oxynorm®, OxyContin®, and Proladone®. It is used for analgesia and is recommended for use in cases of moderate to severe pain.
- **Codeine Phosphate:** Codeine is derived from opium. It modifies the perception of, as well as the emotional response to, pain. It is easily

33 The MIMS Online medicine database is compiled using the Australian Therapeutic Goods Administration (TGA) Approved Product Information that originates from the manufacturer/distributor and is standardised using MIMS Online editorial guidelines. (Accessed at: http://MIMSOnline.hcn.net.au.dbgw.lis.curtin.edu.au/ifmx-nsapi/MIMSOnline-data).

34 Breakthrough pain is a term meaning that pain breaks through normal pain management (or is felt over and above normal pain management) to require a narcotic analgesic.

absorbed. Codeine has three functions as a pharmaceutical: as a cough suppressant, as a mild analgesic with sedative effects for the relief of mild to moderate pain (eg. period pain, tension headache or migraine, pain associated with dental or surgical procedures and neuralgia) and as an anti-diarrhoeal drug (MIMS Online 2003). Codeine has about one-sixth the analgesic activity of morphine. In doses up to 12.8mg, codeine, in combination with other mild analgesics (eg. paracetamol, aspirin), is classified as S3 or S2 and is available in pharmacy only preparations such as Panadeine® and Nurophen Plus® without a prescription. Products containing greater than 15mg of codeine alone, or in compound products, are classified as Schedule 4 drugs for which a prescription is required.

- **Dextropropoxyphene napsylate:** Dextropropoxyphene napsylate (DN) is a synthetic opioid analgesic with a chemical structure similar to that of methadone and a potency of between two-thirds to equal that of codeine. It is available as Doloxene®, with DN as the only active ingredient and as Capadex® or Digesic® in which it is combined with paracetamol. DN preparations are recommended for mild to moderate pain.

Methadone and buprenorphine may be used as narcotic analgesics in the treatment of pain, but they are also used in the treatment of drug dependence, and so will be discussed more fully in the following section.

In summary, narcotic analgesics are available in a variety of forms. They may be used for more minor health problems such as coughs, but are the mainstay of pain management. There are a variety of side effects, and tolerance and dependence can readily develop with continued use. As central nervous system depressants, their effects, and associated risks, are exacerbated when combined with other such depressants.

Opioids used in the management of drug dependence

As well as being used in the treatment of pain, some opioids can be used to treat dependence on other opioids, such as heroin, either to help manage withdrawal or to maintain a patient on a safe dose of the prescribed drug, as opposed to more hazardous use of illicit drugs. Drugs used in the management of opioid dependence have one of three actions:

- Opioid agonist which binds to opioid receptors in the brain and exerts an opioid effect (for example, methadone);
- Partial opioid agonist which exerts a reduced effect on opioid receptors and displaces other opioids (for example, buprenorphine); and
- Opioid antagonist which blocks the brain's opiate receptors and stops other opiates from binding (for example, naltrexone) (Hulse, White & Cape 2002).

Narcotic or opioid antagonists are not considered as drugs of misuse and so will not be discussed here. The two main agonists used in Australia are methadone and buprenorphine.

Methadone

Methadone is a synthetically manufactured opioid agonist which is used as an analgesic and in the management of opioid dependence (MIMS Online 2003). Methadone has a long half-life (13–47 hours, with an average of 24 hours) and has its peak effect after three hours (Ali et al. 2001). In short, its effects are much longer lasting than opioids such as heroin – the effects of the latter may only last two or three hours. Thus, a person on a methadone programme will require a dose every 24 hours on average while a person who is dependent on heroin may require a dose of heroin every four hours in order to avoid withdrawal symptoms. In Australia methadone is available as Methadone Syrup®, containing 5mg methadone per ml, and as Biodone Forte®, oral liquid, also containing 5mg per ml. (Methadone is also available in tablet form and as an injection, under the brand name Physteptone®, for the relief of severe pain.)

In common with all opioids, prolonged use of methadone has the potential to produce dependence, although compared to morphine dependence the withdrawal symptoms are more prolonged but less intense, and with appropriate dosage reduction these symptoms can be managed and consequently are usually mild (MIMS Online 2003).

While methadone can be used in pain management, it is most commonly known for its use in methadone treatment programmes such as:

a) maintenance or long-term program, which may last for months or years, that aims to reduce the harms associated with drug use and improve quality of life; and

b) withdrawal (short-term) detoxification program, which lasts approximately 5–14 days, that aims to ease the discomfort of coming off heroin.[35]

Thus, the aim of the first programme is not abstinence but the stabilisation of the individual and the reduction of other drug-related problems (for example, criminal involvement; blood borne virus transmission):

> Many people believe that it is preferable for heroin users to stop taking drugs altogether. Although for some heroin users this is achievable, for others there is a high risk of relapse into heroin use. Methadone maintenance has helped many people reduce the recurrence of compulsive heroin use.
>
> Methadone treatment, like any other drug treatment, is not a 'cure' for heroin dependence. However, research has shown that it can improve the health of people dependent on heroin in a number of ways:
>
> - people are less likely to use heroin that may be contaminated with other substances;
> - methadone is taken orally, which makes it cleaner and safer than injecting heroin. This reduces the risks of sharing equipment and becoming

35 ADF website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=methadone).

infected with blood-borne viruses such as hepatitis B, hepatitis C (which may lead to long-term liver problems) and HIV – the virus causing AIDS;

- the routine involved in methadone treatment encourages people to lead a balanced and stable lifestyle – including improved diet and sleep;
- people are less stressed, as they do not have to worry about where their next 'hit' of heroin is coming from;
- methadone lasts longer in the body than heroin, so it only has to be taken once a day;
- it allows people to handle the withdrawal process with less discomfort;
- criminal activities conducted to obtain illegal drugs are reduced;
- it helps people cut their connections with the drug scene;
- it's cheaper – although there is usually a dispensing fee with methadone, this is relatively cheap compared to the cost of illicit drug use (the recommended dosage fee at the time of writing this information was $7.50, although this amount may vary between dispensers); and
- under certain conditions, take-away doses of methadone are also available, which help clients return to a more stable lifestyle. To be eligible, clients must meet the criteria as outlined by the state/territory health department as well as those of the methadone prescriber. Some of these criteria include family commitments, illness and travelling long distances.[36]

Use of methadone to treat drug dependence is carefully controlled:

> A person can only become a client on methadone treatment after being assessed by a doctor who is an approved methadone prescriber. In Victoria, doctors must apply to the Drugs and Poisons Unit of the Department of Human Services to become registered as a methadone prescriber. Generally the client should be 18 years of age or over and be physically dependent on opiates. The doctor's assessment takes into account other characteristics such as alcohol or other drug use and psychological health.[37]

As with other forms of drug use, the intended therapeutic effects may be accompanied by unwanted side effects:

> Some people on methadone programs will experience unwanted symptoms during their treatment. These may be caused by the dosage they are receiving being too low or too high, which can occur particularly at the beginning of treatment. Some symptoms may also occur due to the side effects of the drug itself.
>
> Symptoms of the methadone dose being too low may resemble having a bout of the flu. They include: runny nose, sneezing; abdominal cramps; feeling physically weak; loss of appetite; tremors; muscle spasm and jerking; goose

36 ADF website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=methadone).

37 ADF website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=methadone).

> bumps; tears; nausea/vomiting; yawning; diarrhoea; back and joint aches; high temperature but feeling cold; sweating; irritability/aggression/feelings of uneasiness; difficulty sleeping; and cravings for the drug.
>
> A person who suddenly stops taking methadone may experience many of the symptoms listed above. The withdrawal symptoms usually begin one to three days after the last dose, and peak around the sixth day, but can last longer.
>
> Symptoms of too high a dose include: drowsiness/nodding off; nausea/vomiting; shallow breathing; pinpoint pupils; below normal drop in body temperature; slow blood pulse, lowered blood pressure; heart palpitations; dizziness; problems with sexual functioning; and poor blood circulation.
>
> Some people may also experience certain side effects that are unrelated to the dosage including: sweating (clients should drink at least two litres of water per day to avoid dehydration); constipation; aching muscles and joints; lowered sex drive; skin rashes and itching; sedation; fluid retention; loss of appetite, nausea/vomiting; abdominal cramps; tooth decay; and irregular periods.
>
> Side effects should diminish soon after the methadone program is completed. As with all opiates, methadone alone in its pure form will not cause any damage to the major organs of the body. Prolonged use will not cause any physical damage, apart from tooth decay. For those with pre-existing impaired liver function (following conditions such as hepatitis B, hepatitis C infection, or prolonged alcohol use), the methadone dose may require careful monitoring.
>
> People who are not dependent on opiates who take methadone will experience some of the short-term effects similar to those on a methadone program receiving too high a dose (as listed above).[38]

Turning Point Alcohol and Drug Centre adds that the injection of methadone:

> [i]s considered especially problematic as it has unique pharmacological characteristics; building slowly to peak blood levels and has a long half-life, leading to accumulation in the body that can result in toxicity and the increased likelihood of mortality … Injection of both the syrup and tablets is also associated with vascular damage and increased risk of overdose, with injection of syrup independently associated with higher levels of injection-related health problems (Lintzeris, Lenne & Ritter, 1999; Breen et al., 2004; Darke, top & Ross, 2002).[39]

As a central nervous system depressant, the effects can be increased when mixed with other depressants (for example, heroin, alcohol or benzodiazepines), which can increase the risk of overdose. The risk of overdose with methadone alone is also particularly high in the early stages of methadone administration.

38 ADF website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=methadone). See also Chapters 6 and 7 for an account of how methadone prescribing is regulated and overseen by state health authorities.

39 Submission from Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

The equivocal nature of methadone as part of a drug dependence treatment regime is attested to in a review of the research conducted by Caplehorn and Drummer, as outlined in a submission by Turning Point Alcohol and Drug Centre:

> A meta-analysis by Caplehorn and Drummer (2002) of five observational studies, found that while methadone maintenance reduces the mortality of heroin dependent people by 75% by reducing heroin toxicity, the maintenance programs themselves contributed to fatal drug toxicity from diverted methadone preparations. This is particularly the case early in the treatment regimen where short-term elevated risk of fatal iatrogenic toxicity exists (Caplehorn, 1998; Caplehorn and Drummer, 1999). Many overdose deaths where methadone has been implicated have been found to be due to a cocktail of benzodiazepines and opioids (Gibson & Degenhardt, 2005). However Caplehorn and Drummer (2002) found that benzodiazepines were significantly more likely to have contributed to deaths from methadone toxicity among maintenance patients and people taking methadone tablets for pain relief than deaths related to diverted methadone syrup.[40]

Buprenorphine

Buprenorphine is a partial opioid agonist derived from morphine, which is used at low doses for the relief of pain and at high doses for the management of opioid dependency (MIMS Online 2003). In the management of opioid dependency, buprenorphine reduces craving, and prevents opioid withdrawal (Ali et al. 2001). Two buprenorphine products are available in Australia: Subutex®, a sublingual tablet containing 0.4 mg, 2mg or 8mg buprenorphine, and Suboxone® (a combination of buprenorphine and naloxone in a ratio of 4:1) in two strengths, 2mg and 8mg.

In a submission to this Inquiry the Turning Point Alcohol and Drug Centre described the history of buprenorphine use in Australia and Victoria as follows:

> Buprenorphine (Subutex R), an opioid that has been used clinically as an analgesic for many years, and recently introduced in the detoxification and substitution treatment of heroin addiction in many countries, including Australia (in 2000), was initially considered to have lower misuse potential than other opioids such as morphine (Jaffe, 1992). However, several studies have found that it does in fact have such potential (Bedi & Ray, 1998; Bigelow & Preston, 1992; Strain & Walsh, 1997). This potential has lead to a black market in illicitly diverted buprenorphine.
>
> Concurrent with trends in the decreasing use of methadone for drug treatment in Australia, buprenorphine prescriptions increased rapidly (more than twenty-fold) between 1998 and 2002. The trend reflected the drug's uptake as an accepted treatment protocol in 2000, and was approved for PBS prescribing in

40 Submission from Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

> 2001 (TGA, 2003). Uptake of the drug was particularly dramatic in Victoria, which accounted for 48% of all PBS buprenorphine prescriptions in 2002 (at 1,557,734). In January 2006, there were 4,490 registered buprenorphine clients in Victoria.
>
> Illicit use and injection of buprenorphine became more widespread following the heroin drought, although this varies significantly between Australian jurisdictions (Kinner & Fisher, 2002). Reported illicit use and injecting of buprenorphine in Victoria has occurred since the introduction of the drug as a treatment protocol in 2000 (Jenkinson, Miller, & Fry, 2004; Jenkinson & O'Keeffe, 2005; 2006). In 2005, most (85%, n=128) of the Melbourne IDRS [Illicit Drug Reporting System] respondents reported lifetime use of buprenorphine, and 63% (n=94) reported using this drug in the last six months. Three-quarters (76%) of the respondents who reported using buprenorphine in the past six months had mostly obtained it licitly (i.e. with a prescription in their own name; Jenkinson & O'Keeffe, 2006).[41]

When taken orally (swallowed), buprenorphine is metabolised in the small intestine and liver. This significantly reduces its ability to be used to treat drug dependence, and sublingual administration (placed under the tongue until it dissolves – this takes 2–8 minutes, or about 5 minutes on average) is recommended (MIMS Online 2003). Buprenorphine has a half-life of two to five hours but its effects can last up to three days, depending on dose (ADF 2006). Buprenorphine treatment is used for two main purposes:

> [p]reventing withdrawal symptoms, such as cravings for heroin [and] blocking the effects of heroin. Using heroin will not provide the 'high' that would normally be expected, therefore it takes away one of the main reasons to use heroin.[42]

There are a number of advantages of buprenorphine as a maintenance treatment:

> Maintenance treatment holds the person stable while they readjust their lives. The person may decide later to work towards reducing their dose of buprenorphine until they no longer require medical treatment.
>
> Using buprenorphine on its own is unlikely to result in an overdose.
>
> Health problems are reduced or avoided, especially those related to injecting, such as HIV, hepatitis B and hepatitis C viruses, skin infections and vein problems.
>
> Doses are required only once a day, sometimes even less often, because buprenorphine's effects are long lasting.
>
> Buprenorphine is much cheaper than heroin.

41 Submission from Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

42 ADF website (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=buprenorphine).

> Staying off heroin can provide the opportunity to experience more 'life opportunities', such as greater personal happiness, more close and stable relationships with others, employment and more money to buy goods for personal enjoyment.[43]

As with other pharmacotherapies, there are some side effects**:**

> Buprenorphine is generally well tolerated; however, some side effects have been reported. Most of these symptoms occur very early in treatment – in the first week or so. Side effects may be due to the combined experience of withdrawal from opioids and taking buprenorphine. It is important to report any side effects to a health professional.
>
> The most common side effects are similar to those listed under the section 'Buprenorphine withdrawal'. …Withdrawal from long-term use of buprenorphine may produce symptoms similar to those experienced from heroin withdrawal. However, withdrawal symptoms tend to be milder with buprenorphine than those from methadone and other opioids.
>
> Withdrawal symptoms vary from person to person, but may include: cold or flu-like symptoms; headaches; sweating; aches and pains; sleeping difficulties; nausea; mood swings; and loss of appetite.
>
> These effects usually peak in the first two to five days. Some mild effects may last a number of weeks.[44]

Buprenorphine is a central nervous system depressant, and consequently there are risks of using with other depressants. In particular:

> Using benzodiazepines with buprenorphine may lead to breathing difficulties, coma or death.
>
> Using buprenorphine with heroin or other opiates, such as methadone, increases the chances of experiencing ongoing withdrawal symptoms.[45]

Thus, narcotic analgesics are used in the treatment of drug dependence, both to assist withdrawal and as a maintenance treatment to help stabilise an individual patient. Such use is carefully controlled because as well as benefits there are potential risks. In particular, as a central nervous system depressant there is an increased risk if these medications are combined with other depressants.

43 ADF website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=buprenorphine).

44 ADF website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=buprenorphine).

45 ADF website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=buprenorphine).

Conclusion

This chapter has summarised the pertinent medical and pharmaceutical information for the drugs which are the subject of this Inquiry. The information is not exhaustive – it is designed to provide a brief introduction to the area. A variety of medical textbooks are available that can supplement this information for the interested reader who requires more in-depth and sophisticated technical knowledge in this area.[46]

Benzodiazepines and other pharmaceuticals have a legitimate and important role in the treatment of a range of medical and psychological conditions. The problem remains, however, that for all the community perceptions that benzodiazepines and other pharmaceutical drugs are relatively innocuous, all of these medications have varied side effects and the potential to produce dependence. Ascertaining the extent of both licit and illicit use of benzodiazepines and other pharmaceutical drugs is an integral step in formulating policy to address such harmful outcomes of use and is the subject of the following chapter.

46 See for example, Rang, Dale & Ritter 2003, *Pharmacology*, 5th edn, Churchill Livingstone, Sydney.

3. The Extent of Use and Misuse of Benzodiazepines and Other Pharmaceuticals

Introduction

The extent of benzodiazepine and other pharmaceutical drug use and misuse can be demonstrated in part by reviewing a range of available data sources. The purpose of this chapter is twofold. The first is to provide information on the size of the problem of pharmaceutical drug misuse. The second is to provide an overview of the various sources of information available that can inform the shape and conduct of a full Inquiry into this important issue.

As such, the approach taken is not to provide an exhaustive collection of tables and data. Rather, the chapter is very much a scoping piece. It includes a snapshot of international data, including information from the United Nations Office of Drugs and Crime (UNODC) and data from the United States and United Kingdom as examples of the kind of information and data collection systems available overseas. This information not only puts the Australian and Victorian data in context but also provides a basis for seeing how our local systems could be improved, or not, as appropriate.

> The good news is that the increase in invention, production and distribution of controlled prescription drugs has brought relief to millions of people [in the USA]. The bad news is the 94 percent increase in the number of people abusing these drugs between 1992 and 2003, and the 212 percent increase among teens, while the population increased by only 14 percent. The problem of abuse of controlled prescription drugs in America has grown under the counter and under the radar to the point where this abuse now eclipses abuse of all illicit drugs combined except marijuana. The supply often comes from our own medicine cabinets or speedy delivery by ordering over the Internet (National Center on Addiction and Substance Abuse (CASA) 2005, p.1).[47]

47 The problem of prescription drug abuse in the United States has created such concern that recently a United States Congressional Inquiry has been established to investigate the extent of the problem and strategies and interventions to address it. See the United States Congress, Committee on Government Reform, Subcommittee on Criminal Justice, Drug Reform and Human Resources, Hearings into Prescription Drug Abuse. (Accessed at: http://reform.house.gov/CJDPHR/Hearings/EventSingle.aspx?EventID=47888).

Importantly, as has already been noted, the prescription pharmaceutical drugs most prone to misuse are also used legitimately for the appropriate treatment of recognised medical conditions. Thus, understanding misuse of these drugs needs to include consideration of the extent of legitimate use. Furthermore, as the pharmaceutical drugs which are misused are diverted from the chain of legitimate manufacture, supply, prescription, dispensing, and finally use, it is important to have an understanding of the data on the size of the licit pharmaceutical supply and use market as a starting point for any consideration of data pertaining to illicit pharmaceutical access and use. Consequently this chapter begins with a brief summary of data on prescription drug supply as well as the number of prescriptions written for these drugs. Data is provided from the United States, England and Australia.

The next section of the chapter focuses on illicit use. It begins with a summary of the available data sources and their methods and limitations. Illicit drug use, like other illegal behaviour, is by its very nature a hidden activity. Users of illicit drugs are understandably wary of who gets to find out about their behaviour. Therefore it is not possible to get a totally accurate picture of illicit drug misuse. Different research strategies are used to collect data at a population level and in more targeted studies of populations known to be at risk. In the final analysis, what emerges is a patchwork of often overlapping, but different, data sources that nevertheless provide the best available understanding of the nature and extent of illicit pharmaceutical misuse. This patchwork is most valuable when data from different sources converges to a similar finding.

The chapter includes data from primary use sources, that is those surveys and other sources that directly measure use of the drugs, or prescriptions for use in the case of legitimate supply. However, sources that could be considered secondary indicators of use, such as ambulance call-out rates and hospital attendances, are more directly indicators of harm and so are included in Chapter 4, which deals with adverse effects.

Data sources and their limitations

Statistics on licit availability and use of pharmaceutical drugs

International data sources

International data on the availability and supply of drugs of interest to this Inquiry at a global level were very difficult to find. Although statistics from some individual countries are available, data on global manufacture and supply of these drugs is harder to come by. Therefore this Interim Report does not include statistics on international levels of licit pharmaceutical drug supply. However, data on licit pharmaceutical supply in the United States and the England are available and statistics from these countries have been included as examples of the international situation.

United States data sources

In the United States, analysis by the National Centre on Addiction and Substance Abuse (CASA 2005) was conducted on data from two main sources of pharmaceutical drug supply: (i) Data from the Automation of Reports and Consolidated Orders System (ARCOS), which is managed by the Drug Enforcement Agency; and (ii) data from the National Prescription Audit Plus. The ARCOS system covers only 1,100 distributors and manufacturers, which CASA notes is a small fraction of the more than one million distributors and manufacturers registered with the Drug Enforcement Agency. Furthermore, as ARCOS only includes schedule III and IV drugs,[48] benzodiazepine supply data is not included. Data from the ARCOS system is not included in this Interim Report. National Prescription Audit Plus lists the top 200 drugs dispensed to patients from retail pharmacies based on a nationwide survey of 22,000 retail pharmacies and covering some 36 million filled prescriptions. This sample accounts for more than half of all retail pharmacies in the United States (CASA 2005).

English data sources

In England, data was analysed from the Prescription Cost Analysis which is based on information obtained from prescriptions sent for payment to the Prescription Pricing Authority of the National Health Service. Data included prescriptions dispensed in community pharmacies in England, most of which are written by general practitioners in England but include some written by dentists and hospital doctors. Also included are prescriptions written in Wales, Scotland, Northern Ireland and the Isle of Man but dispensed in England. The data do not cover items dispensed in hospital or on private prescriptions. Data is provided at the level of individual drugs, which allows it to be aggregated for different drug classes.

Australian data sources

Australian Statistics on Medicines 2003

In Australia, pharmaceutical prescription data was accessed from publications of the Drug Utilisation Sub-Committee (DUSC) of the Australian Pharmaceutical Benefits Advisory Committee. The DUSC, part of the Australian Government Department of Health and Ageing (DoHA), provides annual estimates of the aggregate community use of prescription medicines in Australia in their *Australian Statistics on Medicines* series (DUSC 2003, 2004, 2005). These publications, and the data set on which they are based, provide a potentially very valuable source of statistics on legal availability of the range of prescription drugs, including those of most interest to the current Inquiry. The data set can be interrogated to produce data at the national and state level. It provides information on the aggregate number of prescriptions written for each specific drug preparation and the aggregate cost to the Pharmaceutical Benefits Scheme (PBS). As an example Table 3.1 provides a small extract from the publication

48 For the most part this is equivalent to Schedule 2 and 3 and some Schedule 4 drugs in Australia (see Chapter 6 of this Interim Report for further discussion of drug scheduling).

Australian Statistics on Medicines 2003, which deals with the class of 'drugs used in the treatment of opioid dependence'. The data comprises estimates based on data about prescriptions submitted for payment of a subsidy under the PBS and Repatriation Pharmaceutical Benefits Scheme (RPBS), along with data from a representative sample of community pharmacies, in order to estimate the non-subsidised use of prescription medicines in the community. Data from these sources is combined into one database to provide an estimate of prescriptions for subsidised and non-subsidised medicines in Australia (DUSC 2005).

The problems with the data are threefold: First, it does not include drugs prescribed in public hospitals, and second, and more significantly, the data is currently published in a raw form. Australian pharmaceutical prescription and supply data has been subject to unpublished analysis that addresses questions of relevance to the current Inquiry (eg. Dobbin 2006, unpublished). However, there has not been a publicly available comprehensive analysis of this data, such as that produced in the United States (CASA 2005). This is needed to inform consideration of pharmaceutical drug misuse and responses to it. Finally, the available data is rarely disaggregated to give 'snapshots' of prescription drug abuse in particular groups, for example among Indigenous or culturally and linguistically diverse communities, for people living in rural and regional areas or among prison populations. Such specialised data should be collected if, as anecdotal evidence strongly suggests, there may be a serious problem of abuse in these groups.[49]

Table 3.1: Sample data from Australian Statistics on Medicines, 2005

ATC	Code	Form And Strength		DDD	Units	Scripts	Cost($)
Drugs used in opioid dependence							
	N07BV01	Buprenophine					
		6307	Sublingual tablet 0.4 mg (base)	8.00	MG	515	–
		6308	Sublingual tablet 2 mg (base)	8.00	MG	8,113	–
		6309	Sublingual tablet 8 mg (base)	8.00	MG	9,909	–
	N07BC02	Methadone Hydrochloride					
		1606	Injection 10 mg in 1 ml	25.00	MG	589	27,204
		1609	Tablet 10 mg	25.00	MG	97,902	1,934,321
		6171	Syrup 25 mg per 5 ml, 200 ml	25.00	MG	11,657	–
		6172	Syrup 25 ml per 5 ml, 1 L	25.00	MG	1,068	–
		17513	Syrup 25 mg per 5 ml, 200 ml	25.00	MG	138,053	–

Note: DDD refers to defined daily dose.
Source: Drug Utilisation Sub-Committee 2005, p.148.

49 For example, a submission to this Inquiry by Darebin City Council stated that with regard to their own research into prescription drug abuse in the Darebin municipality (North East Melbourne): 'Anecdotal evidence from a number of Aboriginal agencies indicated that medication misuse – in particular medication mismanagement – was impacting significantly on Indigenous residents due to the high level of medications many Indigenous people are prescribed.'
It is their view, however, that there is a significant gap in the research (including the collection of extent of use data) that is being done with regard to prescription drug use in Indigenous communities (Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

The Committee also accessed data from the National Drug-control System.

National Drug-control System (NDS) domestic transaction data

Australian pharmaceutical prescription and supply data has been extracted from the National Drug-control System. This is a database programme provided by the United Nations for the purposes of collecting import, export and consumption data and reporting on that data to the International Narcotics Control Board under the terms of international treaties to which Australia is a signatory. Clients (eg. hospitals, doctors, pharmacists etc.) are identified as either 'keeping stock' or 'not keeping stock' in the client master. Clients who do not keep stock are deemed to have consumed the stock. Stock movements can be imported into the National Drug-control System via an EXCEL spreadsheet and movements are tracked on an 'accounting ledger' basis. Once the initial stock levels have been entered, queries can be run on the amounts held for each client by substance or preparation. Transactions can be exported to EXCEL. This Interim Report includes statistics extracted by analysis of this EXCEL data. In Australia the NDS domestic transaction data is collected by the Commonwealth Department of Health and Ageing.

Statistics on illicit use of pharmaceutical drugs

International data sources

The *World Drug Report* is based on data obtained primarily from the annual reports questionnaires forwarded by Governments to the UNODC and is supplemented by other data when necessary and available. Two of the main problems with the report, as acknowledged by UNODC, are that firstly, reporting is unsystematic in terms of the number of countries responding (119 in 2005) and of content; and secondly, few countries have monitoring systems able to produce reliable and comprehensive data which is internationally comparable (UNODC 2006a).

United States data sources

The National Survey on Drug Use and Health (NSDUH) has been conducted in the United States since 1971 with the civilian, non-institutionalised people who are 12 or more years of age. The sample is approximately 67,500 annually. However, in 1998 and 2001 the survey underwent a major redesign (including an incentive payment of $30), suggesting caution in making comparisons between surveys conducted before and after this period. While noting this caution, many sources do make such comparisons, including the CASA (2005) report. The NSDUH focuses on non-medical (ie. not prescribed for the person responding to the questionnaire) use of psychotherapeutic drugs – defined as including sedatives, tranquillisers and analgesics and stimulants (including methamphetamine). Data on pharmaceutical drugs is included, but is not routinely subject to extensive analysis in the NSDUH reports.

Additionally:

> The NSDUH is known to underestimate considerably all forms of substance use in the U.S. Because it is administered in the home, respondents – particularly teens – tend to under-report their substance use. Moreover, the survey does not include high-risk institutionalized populations, such as prison inmates, hospital patients, nursing home residents, patients in drug abuse treatment and others who cannot be reached in a home (e.g., the homeless) (CASA 2005, p.4).

The Monitoring the Future Study, conducted by the University of Michigan's Institute for Social Research, was begun in 1975, as a long-term study of American adolescents, college students, and adults through to age 45. The study has accumulated 31 years of data for students from Grades 8, 10 and 12. It is funded through a series of investigator-initiated, competitive research grants from the National Institute on Drug Abuse. The 2005 Monitoring the Future survey included nearly 50,000 students from Grades 8, 10 and 12 in over 400 secondary schools across the United States (Johnston, O'Malley et al. 2006). The Monitoring the Future study provides an excellent source of data of interest to the current Inquiry, although the way the drug data are clustered and reported makes analysis of some individual drug types problematic. Furthermore, as the data are collected by administering surveys in the classroom, like other surveys of this kind, they are unlikely to reach those young people who may be most at risk of illicit drug use and may not be attending school or may be at school but have trouble completing the questionnaire due to literacy problems.

United Kingdom data

The British Crime Survey collects data from a representative cross-section of households in England and Wales. Since 1996 the survey has included a self-completion module with questions on illicit drug use among 16- to 59-year-olds. An alphabetical class system is used to classify illicit drugs in the United Kingdom. Class A drugs include cocaine, crack cocaine, ecstasy, hallucinogens (LSD and mushrooms) heroin and methadone. Amphetamines can be classified as either Class A, if they are prepared for injection, or Class B, if they are powdered. With respect to 'Tranquillisers', under the United Kingdom system barbiturates are classified as Class B and benzodiazepines as Class C. Due to the nature of this drug classification system and how it is reported in the British Crime Survey, it is only possible to extract estimates of illicit use for methadone and 'tranquillisers' (barbiturates and benzodiazepines combined). Furthermore, with a final sample size of 26,755 (including a booster youth sample) in 2003/04, the sample is comparatively small for countries the size of England and Wales. Like other household surveys, this data is open to the criticism that those who are homeless or institutionalised may be most likely to use illicit drugs but will not be included.

Australian and Victorian data

The National Drug Strategy Household Survey (NDSHS)

The NDSHS has been undertaken in this country on eight occasions, once approximately every three years. Conducted by the Australian Institute of Health and Welfare (AIHW), the NDSHS describes the use of licit and illicit drugs as well as the perceptions and attitudes associated with them among a representative sample of the Australian population aged 14 years and above (although in 2004 a sub-sample of 12- and 13-year-olds was also included) (AIHW 2005a).

Compared to national surveys of drug use in other countries, the Australian NDSHS is considered to be one of the best. However, like other surveys of this kind, it has a number of shortcomings. The NDSHS is conducted as a household survey, therefore those in prison, those in other institutions and the homeless are not included. Furthermore, those with unstable living arrangements are also less likely to be included. With regards to the current Inquiry, it should be noted that the NDSHS does examine the use of painkillers/analgesics and sleeping pills/tranquillisers. However, it does not specifically ask about benzodiazepines. Rather, benzodiazepines are included under the broad heading of 'tranquillisers'. Like other household surveys, because illicit drug use is a hidden activity, rates of illicit drug use based on NDSHS are likely to underestimate the true rates. This is addressed to some extent by guarantees of confidentiality and anonymity and the use of respondent sealed, self-completion sections on drug use. However, it is known that the NDSHS also substantially underestimates the amount of alcohol consumed in Australia, compared to national alcohol sales data (Loxley, Toumbourou & Stockwell 2004), so the problem of under-reporting is not simply about the illegal nature of drug use.

While the NDSHS focuses on non-medical use when inquiring about pharmaceutical drug use, the authors of the 2004 survey report note that in some questions this was not clear, and some respondents may have answered regarding their use of these substances for medical purposes (AIHW 2005a). Furthermore, there have been a number of changes of methodology in the NDSHS over the years including substantial changes in the way questions about lifetime use was measured, and in 2004 Computer Assisted Telephone Interviewing was included for the first time. This makes analysis of trends over time difficult. Another problem with the NDSHS is that of falling response rates. In 1998 the response rate was 56 per cent, in 2001 it was 51 per cent and in 2004 it was 46 per cent (AIHW 2005b). Loxley, Toumbourou, and Stockwell (2004) noted that the drop in response rate is of concern, as those who don't participate, for whatever reason, are likely to be heavier users.

The Illicit Drug Reporting System (IDRS)

The IDRS is an ongoing illicit drug monitoring system coordinated nationally by the National Drug and Alcohol Research Centre and funded by the DoHA

and the National Drug Law Enforcement Research Fund. It has been conducted in all Australian jurisdictions since 2000. It aims to provide a coordinated approach to monitoring the use of illicit drugs – in particular, heroin, methamphetamine, cocaine and cannabis – and to identify emerging trends of local and national concern in illicit drug markets (Stafford, Degenhardt, Black et al. 2006). The IDRS collects data from three sources: interviews with a minimum of 100 injecting drug users in each jurisdiction; interviews with key experts who have regular contact with illicit drug users; and an examination of existing indicator data from the health and law enforcement sectors (Stafford, Degenhardt, Black et al. 2006).

To be eligible for the IDRS injecting drug users survey, such users must have injected an illegal drug on at least a monthly basis for the previous six months. Questions are asked about the range of other drugs including those pharmaceutical drugs often misused by injecting drug users. However, the degree to which particular pharmaceutical drugs are addressed varies, but has been improving over recent years as concern about pharmaceutical drug misuse has increased. The strength of the IDRS is that it is nationally conducted and provides comparable data on trends over time. The main disadvantage is that the IDRS provides summary quantitative data and not the detail required to understand the experience of users behind the basic prevalence data. Of course, as the IDRS focuses on data from only recent injecting drug users, information from this survey is not representative of illicit drug use in the general population. Data from both the national (eg. Stafford, Degenhardt, Black et al. 2006) and Victorian reports (eg. Jenkinson & O'Keefe 2006) are included in this chapter.

The Party Drugs Initiative

Also coordinated nationally by the National Drug and Alcohol Research Centre, the Party Drugs Initiative (PDI) is an offshoot of the IDRS and aims to identify emerging trends of jurisdictional and national interest in ecstasy and related drug markets. The PDI has been conducted in each Australian capital city since 2003. It comprises three components: interviews with at least 100 regular ecstasy users (defined as those having used ecstasy at least six times in the preceding six months); interviews with key informants who are professionals in frequent contact with regular ecstasy users; and analysis and examination of indicator health and law enforcement data. Like the IDRS, the PDI is designed to be sensitive to emerging trends, providing data in a timely manner, rather than describe issues in extensive detail, so data is limited to basic prevalence and use information. Results from the surveys of regular ecstasy users are not representative of ecstasy users as a whole, or of use in the general population. Like the IDRS, the strength of the PDI data is its capacity to monitor trends over time in a sentinel population of drug users, which can act as an early warning system detecting emerging drug trends (Stafford, Degenhardt, Dunn et al. 2006).

The Australian Secondary Students' Alcohol and Drug (ASSAD) Survey 2002

The ASSAD is coordinated nationally and within Victoria by the Centre for Behavioural Research in Cancer on behalf of the Drug Treatment Services Unit, DHS Victoria. A representative sample of schools are selected randomly from all government and non-government schools in Victoria, with up to 80 students from each of 66 schools being surveyed in 2002. Data was collected on tobacco, alcohol, cannabis, inhalants and some other illicit substances, with the 2002 report being based on data from 4,111 students aged 12 to 17 years.

Drug Use Monitoring in Australia (DUMA)

Commenced in 1999, the DUMA programme is a quarterly collection of information from police detainees in seven police stations or watch-houses across Australia, although none of these are in Victoria. DUMA collects data from two sources: a questionnaire, which is conducted with a trained interviewer, and a urine sample tested for six different drug classes. Both sources of information are collected on a voluntary basis and neither can be linked back to the detainee (Schulte, Mouzos & Makkai 2005).

The Victorian Youth Alcohol and Drugs Survey

The Victorian Youth Alcohol and Drugs Survey is an interview study that measures drug use and attitudes regarding alcohol and illicit drugs among young Victorians aged 16–24 years. Three Victorian Youth Alcohol and Drugs surveys were conducted annually between 2002 and 2004. The 2002 survey was conducted in three separate waves in March, June and September among a total of 4,500 young Victorians aged 16–24 years. The 2003 survey was conducted in two waves of approximately 3,000 respondents each in February/March and November/December 2003. The 2004 survey was conducted in a single wave of 6,005 interviews during the period November 2004 to January 2005. The Victorian Youth Alcohol and Drugs Survey employs computer-assisted telephone interviewing using randomly selected telephone numbers from electronic *White Pages* and consequently no homeless or institutionalised persons are included (Premier's Drug Prevention Council 2005). As a result, prevalence of drug use reported is likely to be an underestimate.

DirectLine

DirectLine provides a 24-hour telephone counselling, information and referral service for Victorians wishing to discuss drug-related issues. The service receives calls from individual drug users, relatives and friends of drug users, people seeking drug information generally and professionals in related services fields (DHS Victoria 2006e). As such, analysis of DirectLine calls can be seen as a measure of general levels of drug use and concern in the community, but it is not possible from the summary statistics collected and analysed to determine whether the calls related to licit or illicit use of the drugs of interest to this Inquiry.

In summary, the data available includes a patchwork of imperfect data sources. The Victorian based Turning Point Alcohol and Drug Centre also agrees that the current system of data collection and dissemination is limited and has suggested that:

> In regards to future research priorities, the ongoing monitoring of trends in both licit and illicit use of benzodiazepines and pharmaceutical opiods is warranted. Particular areas to focus on in such surveillance are key illicit market indicators such as price, supply source and availability, as well as the adverse health and other outcomes associated with pharmaceutical misuse. Because of the nature of the use, relatively little is known about pharmaceutical misuse in the general population compared with IDU [injecting drug users]. Mechanisms to monitor trends in such use, such as the linking of databases and the routine surveillance of indicator data (e.g. ambulance attendances, help line contacts, treatment databases) need to be explored.[50]

Nonetheless, with regards to data on pharmaceutical drug availability and supply, the raw data collected in Australia appears to be at least as good as that collected in the United States and United Kingdom. However, it has not been subject to the kind of comprehensive and publicly available analysis provided in the United States in CASA's (2005) report, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.*, which will be discussed further in the next section.

Summary

Australian and Victorian data sources bearing on illicit drugs availability and use among the general population and subgroups of interest such as young people, injecting and party drug users, is particularly useful. Although, with regards to the current Inquiry, at times the data is limited by the manner in which use of pharmaceutical drugs are recorded and reported. Furthermore, the sampling strategies employed necessarily require caution in generalising results. Notable in this regard is the likely under-reporting of drug use rates caused by biases resulting from the use of household samples. However, the data available and summarised in this chapter provide the best available understanding of the nature and extent of illicit pharmaceutical misuse in Victoria and elsewhere.

Statistics on licit availability and use

International data

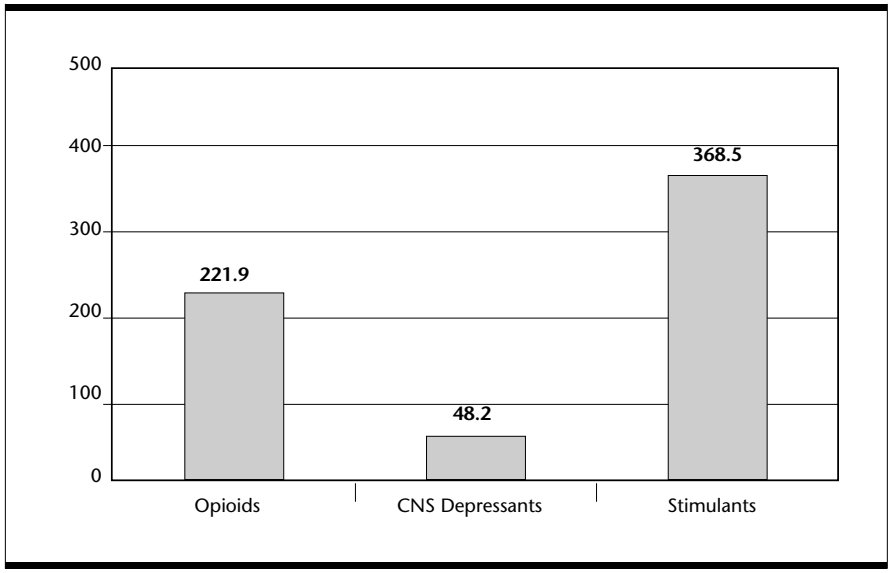
United States data

One of the best sources of international data on the extent of use and misuse of benzodiazepines and other prescription drugs is the work done in the United States by CASA (2005). This comprehensive report, entitled *Under the Counter:*

50 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

The Diversion and Abuse of Controlled Prescription Drugs in the U.S., is based on CASA's three-year study on the diversion and abuse of prescription drugs with the potential for abuse and addiction (termed 'controlled drugs').

Figure 3.1: Per cent increase in prescriptions filled for controlled drugs, USA, 1992–2002



Note: Central nervous system depressants includes benzodiazepines and barbiturates.
Source: National Center on Addiction and Substance Abuse (CASA) 2005, p.26.

CASA concluded that while the United States population had increased by 13 per cent between the years 1992 and 2002, the number of prescriptions written for controlled drugs increased by 154.3 per cent, 12 times faster than the population growth and almost three times faster than the growth in non-prescription drugs over the same period (CASA 2005). Figure 3.1 presents percentage increases in prescriptions filled for opioids, central nervous system depressants (barbiturates and benzodiazepines) and stimulants over this period. Tables 3.2 and 3.3 show the percentage changes for benzodiazepine and opioid prescriptions over the same period. These tables indicate that prescriptions for opioids as a whole rose by 222 per cent and for benzodiazepines by 49 per cent.

CASA also argued that while this increase could have been a function of improved treatment for the range of conditions treated by these medications, they found that the number of people who admitted 'abuse' of these medications increased some 94 per cent from 7.8 million in 1992 to 15.1 million in 2002, a rate seven times greater than the population growth (CASA 2005).

Table 3.2: Per cent change in benzodiazepine prescriptions filled, USA, 1992–2002

Benzodiazapine Prescriptions Filled (000s)			
Benzodiazepine	**1992**	**2002**	**percent change**
clonazepam (e.g. Klonopin)	2,286	8,040	+252
diazepam (e.g. Valium)	8,358	8,265	-1
estazolam (e.g. ProSom)	0	115	+115
lorazepam (e.g. Ativan)	7,449	12,068	+60
triazolam (e.g. Halcion)	2,091	760	-64
Total	**20,091**	**29,248**	**+49**

Note: In NPA data "0" indicates that the volume of prescriptions filled was between 1 and 499.
Source: National Center on Addiction and Substance Abuse (CASA) 2005, p.26.

Table 3.3: Per cent change in opioid prescriptions filled, USA, 1992–2002

Opioid Prescriptions Filled (000s)			
Opioid	**1992**	**2002**	**percent change**
codeine	9,120	10,169	+12
fentanyl (e.g. Sublimaze)	341	4,111	+1,106
hydrocodone (e.g. Vicodin)	15,843	75,357	+376
hydromorphone (e.g. Dilaudid)	380	785	+107
merperdine	1,039	1,728	+66
methadone	107	1,816	+1,597
morphine	715	2,706	+279
oxycodone (e.g. OxyContin)	5,641	27,053	+380
Total	33,186	123,725	+222

Source: National Center on Addiction and Substance Abuse (CASA) 2005, p.26.

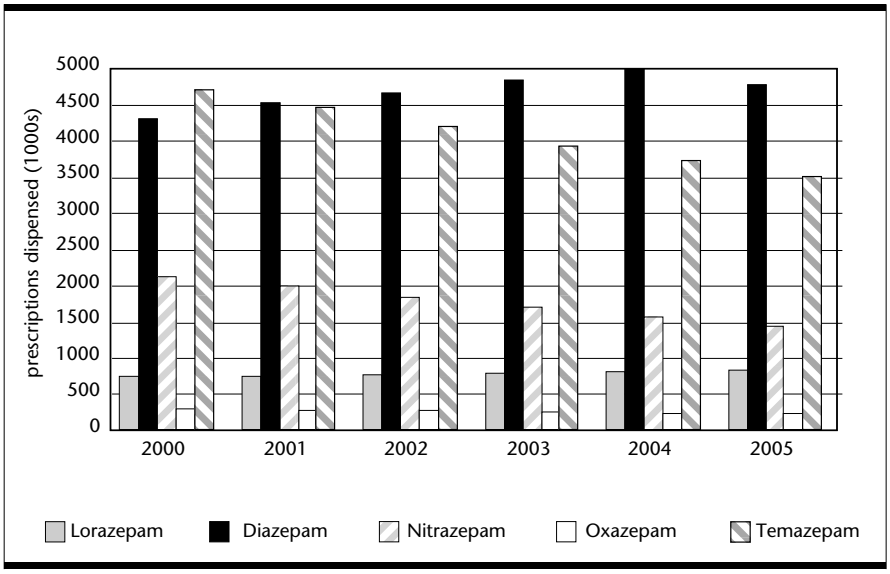
Of particular concern to CASA was the growth in prescription drug abuse among those under 18 years. It was estimated that in 2003, 9.3 per cent (2.3 million persons) of young people aged 12 to 17 years used a controlled prescription drug in the past year, 83 per cent being opioids. Over the period 1992 to 2002, the rate of increase in prescription drug use was 216 per cent, some 2.6 times greater than the 81 per cent increase among those aged 18 years and over. Those who had abused a prescription drug were far more likely to have used a range of other illicit drugs. The researchers noted that steroid use was a growing problem among teens, with use among high school students increasing 126 per cent between 1991 and 2003. They also noted that the rate of increase was far greater among girls (342%) than boys (66%) (CASA 2005). As stated earlier in this chapter, the types of concerns expressed by CASA and illustrated in the data above have in part resulted in a Congressional Inquiry into prescription drug abuse in the United States.[51]

51 See http://reform.house.goc/CJDPHR/Hearings/EventSingle.aspx?EventID-47888

English data

An analysis of benzodiazepine prescriptions written by general practitioners, dentists and nurse practitioners in England in settings other than hospitals found that over the period 2000 to 2005 there was a decrease in numbers of prescriptions for temazepam (from 4,696,900 in 2000 to 3,492,900 in 2005) and Nitrazepam (from 2,094,900 in 2000 to 1,422,900 in 2005) and an increase in diazepam prescribing (from 4,923,300 in 1999 to 4,748,500 in 2005) (see Figure 3.2) (Department of Health (England), 2001, 2002, 2003, 2004, 2005, 2006).

Figure 3.2: Prescriptions of selected benzodiazepines dispensed in England, 2000–2005 (in 1000s)



Source: Data extracted by the National Drug Research Institute (NDRI) from Department of Health (England), 2001, 2002, 2003, 2004, 2005, 2006.

Over the period 2000 to 2005 there was a large increase in the number of prescriptions written for some narcotic analgesics in the England. Table 3.4 shows that there was a gradual increase in the number of prescriptions written for morphine sulphate over this period while prescriptions for oxycodone increased more than 16-fold over the period and those for tramadol more than doubled. The other observation of note is that since 2000 tramadol accounted for many more prescriptions than the other two drugs combined.

Table 3.4: Prescriptions of selected narcotic analgesics dispensed in England, 2000–2005 (in 1000s)

	Morphine sulphate	Oxycodone hydrochloride	Tramadol hydrochloride
2000	865.5	17.5	1,511.0
2001	942.2	57.8	1,869.9
2002	970.6	101.4	2,256.9
2003	1,029.1	144.9	2,656.1
2004	1,113.4	208.4	3,129.7
2005	1,238.5	295.7	3,654.7
Total	**6,159.3**	**825.7**	**15,078.3**

Source: Data extracted by the National Drug Research Insitute (NDRI) from Department of Health (England), 2001, 2002, 2003, 2004, 2005, 2006.

Australian data

The statistics on licit supply and use of selected pharmaceutical drugs in Australia presented here are primarily from two major sources. Firstly, data has been extracted from the *Australian Statistics on Medicines* series which shows the number of prescriptions subsidised by the PBS/RPBS dispensed in community pharmacies and estimates of non-subsidised supply based on a sample of community pharmacists. Secondly, very useful data from the unpublished work of Dobbin (2006a, b, c, d, e) is also used which shows how PBS and similar data on pharmaceutical drug supply can be analysed and presented in such a way as to provide useful trend data which addresses questions of interest to the current Inquiry.

Benzodiazepines

Data extracted from the *Australian Statistics on Medicines* series presented in Table 3.5 below shows the number of prescriptions (subsidised by the PBS) for each kind of benzodiazepine across Australia. It shows that for the period 1999 to 2003 the number of benzodiazepine prescriptions in Australia has decreased for all types apart from alprazolam, and that, in particular, temazepam prescriptions have declined as a proportion of total benzodiazepine prescriptions from 39.26 per cent to 36.59 per cent over that period.

Table 3.5: Number of subsidised PBS/RPBS prescriptions for benzodiazepines dispensed through community pharmacies in Australia, 1999–2003

	1999	2000	2001	2002	2003
Alprazolam[a]	353732 (4.09%)	389249 (4.54%)	418960 (5.01%)	432337 (5.41%)	449127 (5.81%)
Bromazepam[b]	45312 (0.52%)	42506 (0.50%)	42264 (0.51%)	40313 (0.50%)	40819 (0.53%)
Clonazepam[c]	116049 (1.34%)	121504 (1.42%)	122148 (1.46%)	111770 (1.40%)	102111 (1.32%)
Diazepam[d]	1977892 (22.87%)	2007593 (23.43%)	2005620 (24.00%)	1968907 (24.62%)	1960086 (25.36%)
Flunitazepam[e]	85069 (0.98%)	11470 (0.13%)	13824 (0.17%)	65518 (0.82%)	71831 (0.93%)
Nitrazepam[f]	935324 (10.81%)	880665 (10.28%)	822804 (9.85%)	789106 (9.87%)	753108 (9.74%)
Oxazepam[g]	1740623 (20.12%)	1699806 (19.84%)	1621204 (19.40%)	1559090 (19.49%)	1524567 (19.72%)
Temazepam[h]	3395474 (39.26%)	3415033 (39.86%)	3308723 (39.60%)	3031290 (37.90%)	2828158 (36.59%)

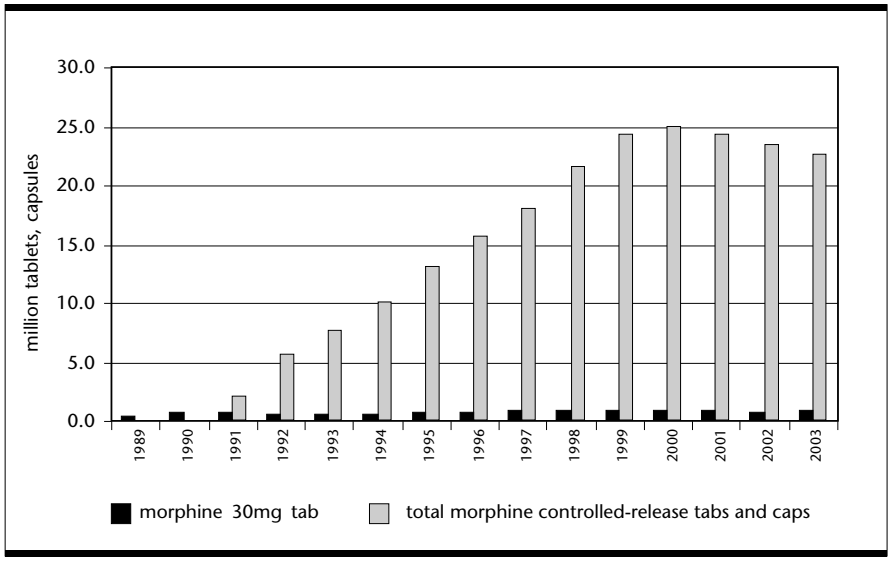
Notes: a Brandname Xanax or Kalma.
b Brandname Lexotan.
c Brandname Rivotril.
d Brandname Valium, Ducene or Antenex.
e Brandname Hypnodorm or Rohypnol.
f Brandname Mogodon or Alodorm.
g Brandname Serepax, Murelax or Alepam.
h Brandname Euhypnos, Nocturne, Normison.

Source: Data extracted from the Drug Utilisation Sub-Committee of the Australian Pharmaceutical Benefits Advisory Committee 2003, 2004, 2005.

Morphine

Dobbin (2006b, unpublished) presents data on the supply of immediate release and controlled release morphine preparations in Australia. Controlled release tablets (MS Contin®) were introduced in Australian in 1991 and capsules (Kapanol®) in 1992. Over the period 1990 to 2003 the total number of morphine tablets and capsules provided in Australia has increased from 651,360 to 25.7 million, representing a 40-fold increase (see Figure 3.3).

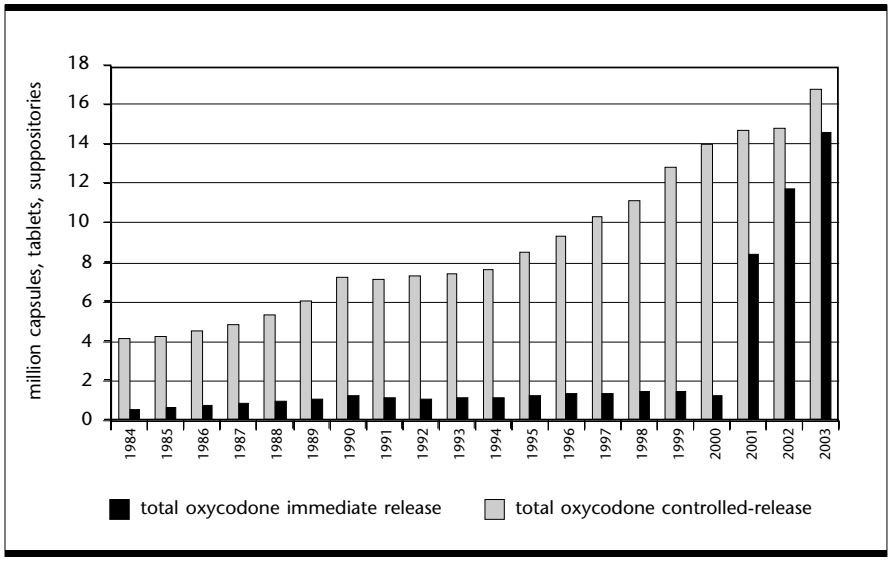
Figure 3.3: Morphine tablet and capsule supply, Australia, 1989–2003



Source: Dobbin 2006b, 'Morphine', Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data, collected by the Commonwealth Department of Health and Ageing.

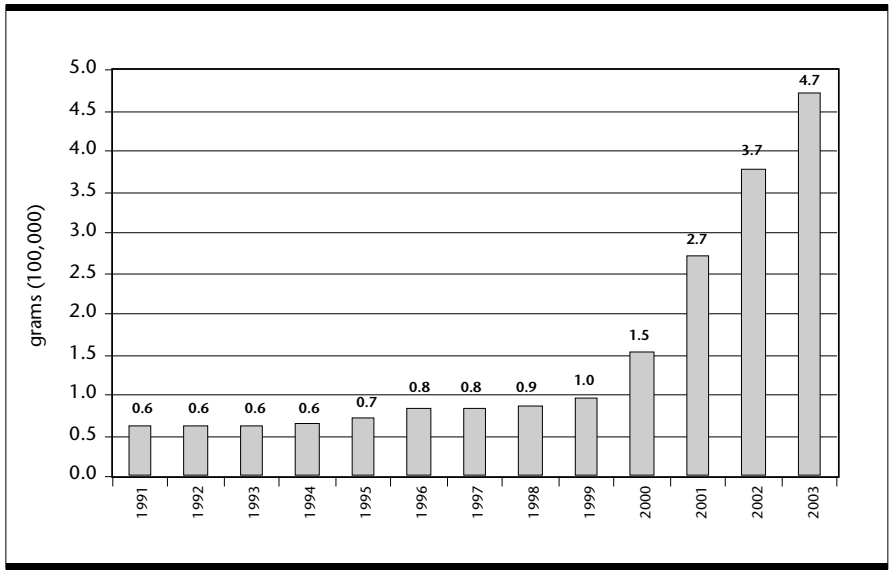
Dobbin (2006c, unpublished) has also used the data to track the growth of oxycodone supply in Australia, subsequent to the introduction of controlled release oxycodone tablets in 2001. This is apparent in Figure 3.4 and Figure 3.5, showing trends in oxycodone tablet, capsule and suppository supply in Australia and the resulting net increase in base grams of oxycodone. The total number of oxycodone capsules, tablets and suppositories supplied in Australia has grown from 8.4 million in 1990 to 31.4 million in 2003, representing a 3.75-fold increase.

Figure 3.4: Oxycodone tablet, capsule and suppository supply, Australia, 1984–2003



Source: Dobbin 2006c, 'Oxycodone', Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data, collected by the Commonwealth Department of Health and Ageing.

Figure 3.5: Oxycodone base supply (grams) Australia, 1991–2003



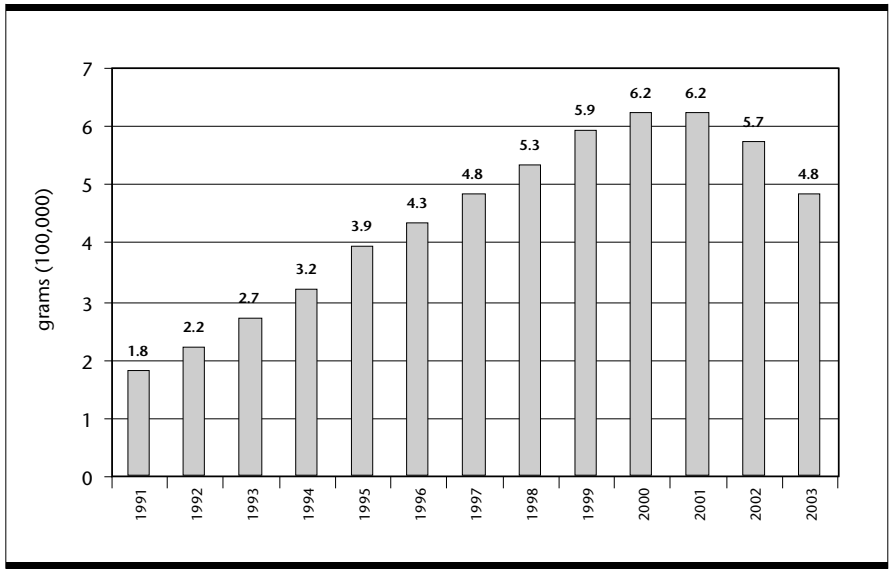
Source: Dobbin 2006c, 'Oxycodone', Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data, collected by the Commonwealth Department of Health and Ageing.

Methadone

With regards to methadone, Dobbin's (2006d, unpublished) analysis shows similar trends in supply. Thus Figure 3.6 shows that the total volume of

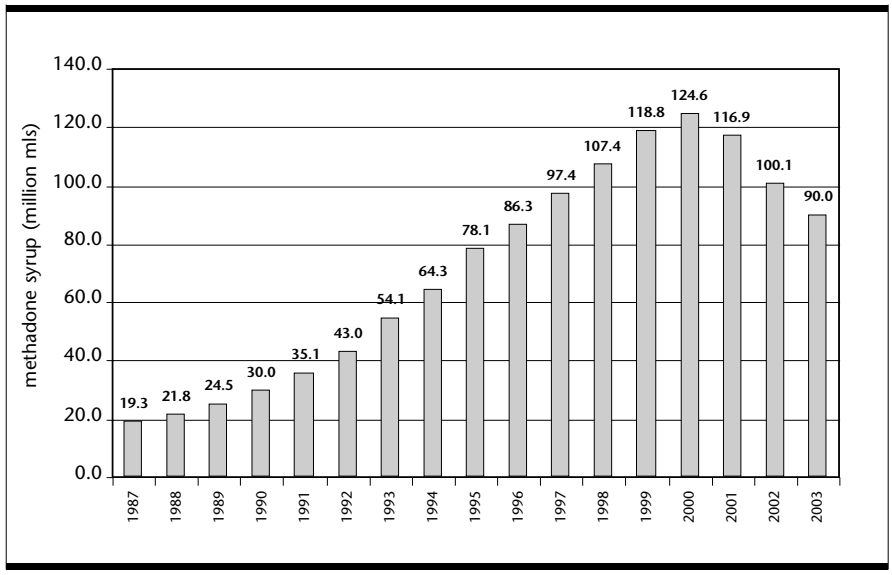
methadone base supplied in Australia rose from some 1.8 million grams in 1991 to a peak of 6.2 million grams in 2001 and has subsequently decreased. This decrease appears due to a decrease in both methadone syrup (see Figure 3.7), which Dobbin (2006d, unpublished) puts down to the introduction of buprenorphine for the treatment of opioid dependence in 2001, and methadone tablets (see Figure 3.8), which he believes may be due to the marked increase in sustained release morphine and oxycodone preparations.

Figure 3.6: Methadone base supply, Australia, 1991–2003



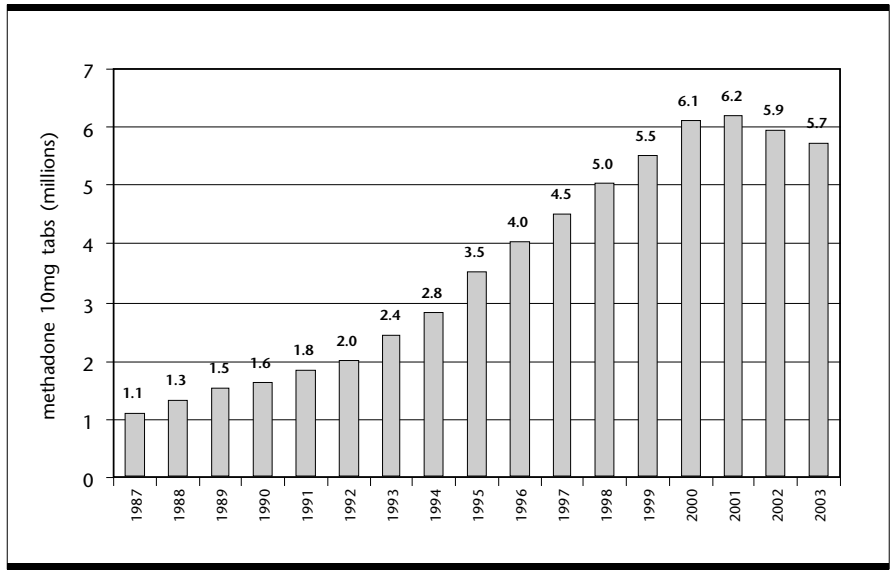
Source: Dobbin 2006d, 'Methadone', Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data, collected by the Commonwealth Department of Health and Ageing.

Figure 3.7: Methadone syrup (5mg/ml) supply (million ml), Australia, 1987–2003



Source: Dobbin 2006d, 'Methadone', Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data, collected by the Commonwealth Department of Health and Ageing.

Figure 3.8: Methadone 10mg tablet supply, Australia, 1987–2003



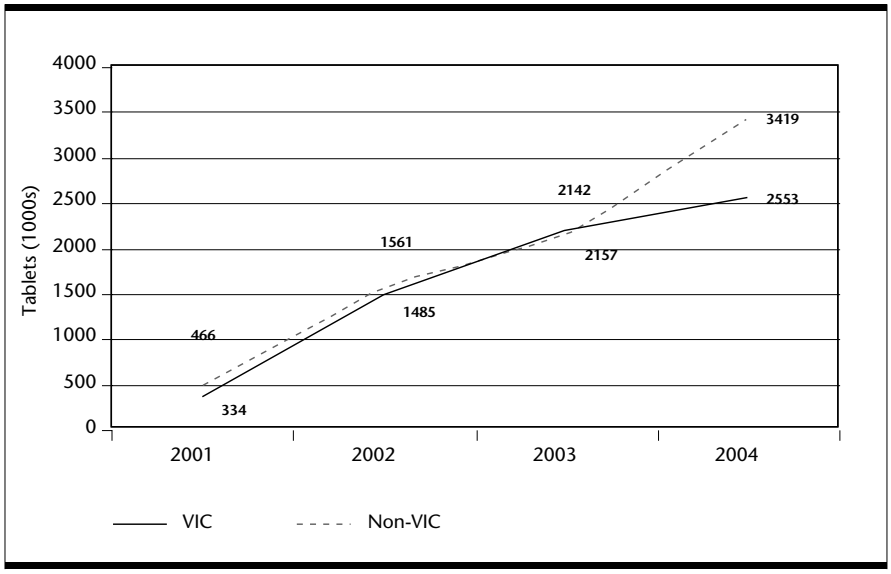
Source: Dobbin 2006d, 'Methadone', Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data, collected by the Commonwealth Department of Health and Ageing.

Buprenorphine

Data on trends in buprenorphine supply in Australia supplied by Dobbin (2006e, unpublished) demonstrates both the growth in the availability of this

drug since it was introduced in 2001 and that the number of tablets dispensed in Victoria roughly equalled all those dispensed in Australia until 2003, after which time buprenorphine treatment for opiate dependence was increased in other Australian jurisdictions (see Figure 3.9).

Figure 3.9: Trends in buprenorphine supply in Australia, 2001–2004



Source: Dobbin 2006e, 'Buprenorphine', Unpublished paper provided to the Drugs and Crime Prevention Committee. Data extracted from the National Drug-control System (NDS) domestic transaction data, collected by the Commonwealth Department of Health and Ageing.

Victorian data

Benzodiazepines

Benzodiazepines are among the most widely prescribed drugs in Victoria with some 1.75 million prescriptions issued under the PBS in the state in 2004. In addition there are also those that are dispensed on private, non-PBS prescriptions and large numbers dispensed by hospitals throughout the state, which are not included in this count (DHS Victoria 2006e). Table 3.6 shows that temazepam, diazepam and oxazepam together comprise 82 per cent of all benzodiazepine prescriptions dispensed in 2004. While there have been a number of changes in the numbers of individual benzodiazepines prescribed in Victoria over time, most notable has been a decrease in the numbers of temazepam prescriptions, across Australia. This has occurred since the availability of the capsule formulation as a PBS pharmaceutical benefit was severely curtailed in May 2002. Evidence was shown that there was a widespread problem of injection of the liquid contents of the capsules by injecting drug users, resulting in serious tissue and vascular harm (Dobbin et al. 2003).[52] Consequently, in Victoria, prescriptions for temazepam fell by 13 per cent in 2002, 7 per cent in 2003 and 2 per cent in 2004. As a result of the

52 See also discussion in Chapters 4 and 8 of this Interim Report.

changes to regulations, temazepam 10mg capsules, which had been demonstrated as often abused by injecting drug users, required approval from the Health Insurance Commission (HIC) before they could be dispensed under the PBS. However, no such condition was placed on 10 mg temazepam tablets, which were less readily injectable. Subsequently in 2004 temazepam gel capsules were withdrawn from the market (DHS Victoria 2006e).

Table 3.6: Numbers of subsidised PBS/RPBS prescriptions for benzodiazepines dispensed through community pharmacies in Victoria, 1999–2004

Generic name	1999	2000	2001	2002	2003	2004
Alprazolam[a]	82,377 (4.34%)	94,892 (4.84%)	104,230 (5.42%)	113,114 (6.27%)	119,284 (6.8%)	126,763 (7.3%)
Bromazepam[b]	468 (0.03%)	452 (0.02%)	455 (0.02%)	498 (0.03%)	475 (0.03%)	496 (0.03%)
Clonazepam[c]	16,451 (0.87%)	17,070 (0.87%)	17,364 (0.90%)	16,481 (0.91%)	14,426 (0.83%)	14,370 (0.83%)
Diazepam[d]	449.232 (23.66%)	469.234 (23.98%)	469.681 (24.44%)	463.076 (25.66%)	460.645 (26.36%)	471.897 (27.1%)
Flunitrazepam[e]	1,777 (0.09%)	1,568 (0.08%)	1,462 (0.08%)	652 (0.04%)	1,177 (0.07%)	1,124 (0.07%)
Nitrazepam[f]	207,382 (10.92%)	199,931 (10.22%)	188,006 (9.78%)	181,056 (10.03%)	173,776 (9.94%)	164,935 (9.46%)
Oxazepam[g]	376,452 (19.83%)	377,040 (19.27%)	363,307 (18.90%)	352,141 (19.51%)	347,044 (19.86%)	344,171 (19.75%)
Temazepam[h]	764,720 (40.27%)	796,592 (40.71%)	777,429 (40.45%)	677,947 (37.56%)	630,863 (36.10%)	618,970 (35.52%)
Total	1,898,859 (100%)	1,956,779 (100%)	1,921,934 (100%)	1,804,965 (100%)	1,747,690 (100%)	1,742,726 (100%)

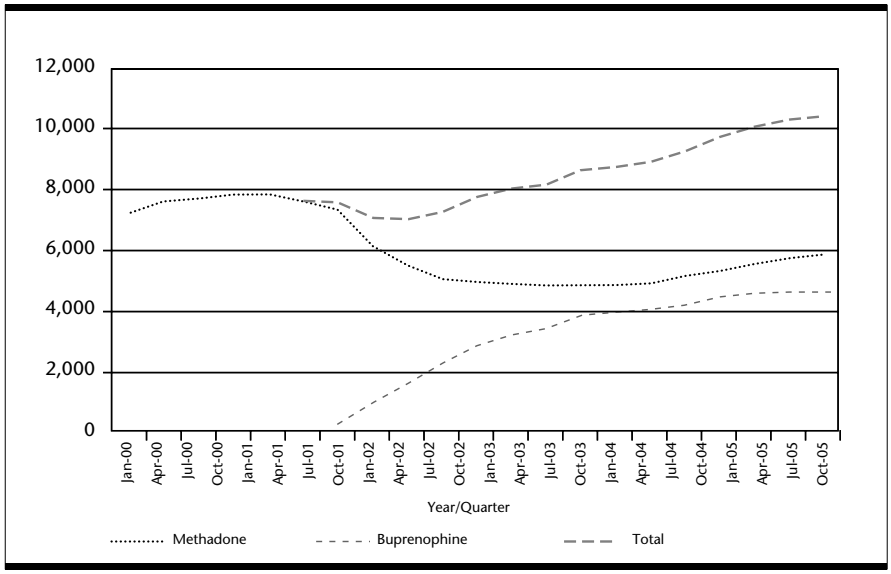
Notes: a Brandname: Xanax or Kalma.
b Brandname: Lexotan.
c Brandname: Rivotril.
d Brandname: Valium, Ducene or Antenex.
e Brandname: Hypnodorm or Rohypnol.
f Brandname: Mogadon or Alodorm.
g Brandname: Serepax, Murelax or Alepam.
h Brandname: Euhypnos, Nocturne, Normison, Temaze or Temtabs

Source: Department of Human Services (DHS) Victoria 2006e, p.55.

Trends in use of methadone and buprenorphine in opioid treatment

Changes in the patterns of supply of methadone and buprenorphine at a national level are reflected in data provided below which shows the trends in the numbers of Victorians enrolled in methadone and buprenorphine treatment programmes in this state. This is presented in Figure 3.10.

Figure 3.10: Number of clients on methadone or buprenorphine in Victorian drug treatment programmes per quarter, January 2000 to January 2005



Source: Department of Human Services (DHS) Victoria 2006e, p.84.

Methadone

Data from the National Drug-control System (NDS) database shows that there is a great deal of variability between jurisdictions in the proportion of methadone (by weight) supplied by tablets as opposed to syrup. Overall, in 2003 some 11.3 per cent of the methadone supplied in Australia was in tablet form, while in Victoria the figure was slightly less at approximately 9.3 per cent (NDS domestic transaction data 2006).

Buprenorphine

Given Victoria's role in the piloting of the use of buprenorphine for the treatment of opioid addiction in Australia, it is not surprising that NDS data reveals that as at 2004, Victoria had the largest proportion of all the buprenorphine dispensed in Australia. This amounted to 43 per cent of the national total (NDS domestic transaction data 2006).

Summary

There are three summary points to be made in relation to the data presented here on licit availability and supply of these pharmaceutical drugs. First, in Australia as in the United States and England, over recent years there appears to have been a substantial increase overall in the total numbers of these drugs in the community, as indicated by the number of community prescriptions and other indicators of supply. Second, the increases are not universal across substances or locations. For example, numbers of benzodiazepine prescriptions as a whole have decreased in Victoria since 1999. However, over the last one to

two decades we have seen large increases in the supply of a range of narcotic analgesics into the Australian community. While recognising that much of this supply may be reflective of better pain management and other improvements in treatment for a range of conditions, it nevertheless also represents an increase in the total supply potentially available for diversion and non-medical use. Third, as a result of changes in prescribing practices and regulations to both improve treatment options and reduce unintended consequences of misuse, there has been a decrease in the availability of some drugs. One such example is the decrease in methadone supply in Victoria and elsewhere as buprenorphine has been introduced and its use expanded as a treatment for opiate addiction. Another example is the impact of the restrictions on availability of gel caps of temazepam, initially by changing their eligibility for a subsidy as a PBS pharmaceutical benefit in 2002 and then their removal from sale in 2004. The next section will provide statistics on the extent and trends in illicit use of benzodiazepines and narcotic analgesics.

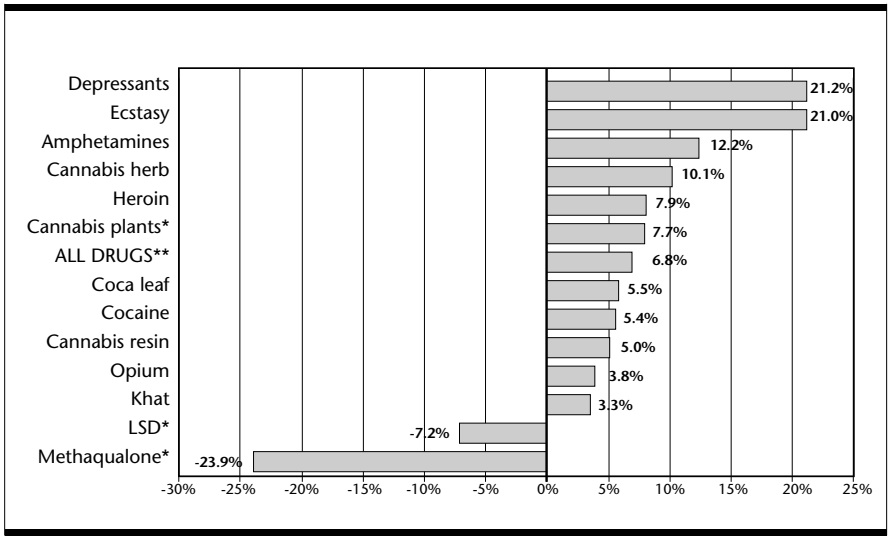
Illicit use

International data – a snapshot

UN data

According to the UNODC, globally the strongest increases in weight of drugs seizures over the 1994–2004 period were for depressants, primarily diverted benzodiazepines and barbiturates, which on average have increased by 21 per cent annually. This rate of increase in total weight seized was equalled only by ecstasy in the same period (see Figure 3.11). However, this increase is offset by the fact that the actual quantity of pharmaceutical depressants seized was quite low, as can be seen in Table 3.7 (UNODC 2006a). Although too detailed to show here, the UNODC presents drug seizure data by drug type for each country and year for the period 1999 to 2004 (UNODC 2006b).

Figure 3.11: Average international annual change in drug seizures, 1999–2004



Notes: *seizures in units
**seizures transformed into unit equivalents
Source: United Nations Office of Drugs and Crime (UNODC) 2006a, p.45.

Table 3.7: Largest quantities of drugs seized internationally in 2004 (rounded to the nearest ton)

Drug	Quantity in tons
Cannabis herb	6,200
Cannabis resin	1,500
Coca leaf	1,200
Cocaine	590
Opium	210
Herin and Morphine	100
Khat	97
Amphetamines	20
Ecstasy	8
Methaqualone	5
Other depressants	2

Source: United Nations Office of Drugs and Crime (UNODC) 2006a, p.43.

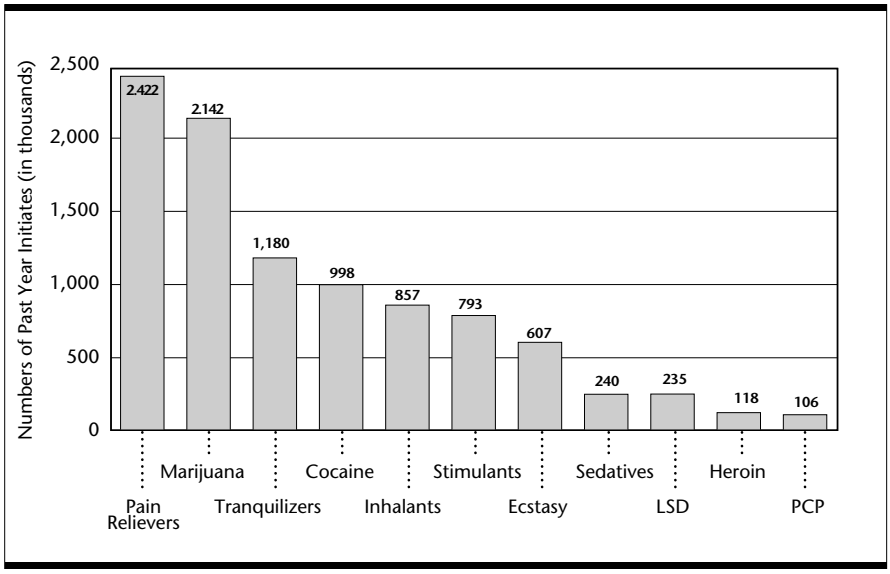
United States data

Approximately six percent of the U.S. population (15.1 million people) admitted abusing controlled prescription drugs in 2003, 23 percent more than the combined number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (328,000) (CASA, 2005, p.3).

National Survey on Drug Use and Health (NSDUH)

Data from the NSDUH in 2004 includes the numbers who were 'new initiates' to illicit use in that year; that is, they began illicit use of the drug for the first time in that year. Figure 3.12 shows that the category with the largest number of new users in that year was non-medical use of (prescription) pain relievers (2.4 million), followed by cannabis (2.1 million) and non-medical use of tranquillisers (1.2 million) (primarily benzodiazepines). Thus, illicit users of prescription analgesics and benzodiazepines accounted for significant proportions of new users of illicit drugs in the United States in 2004.

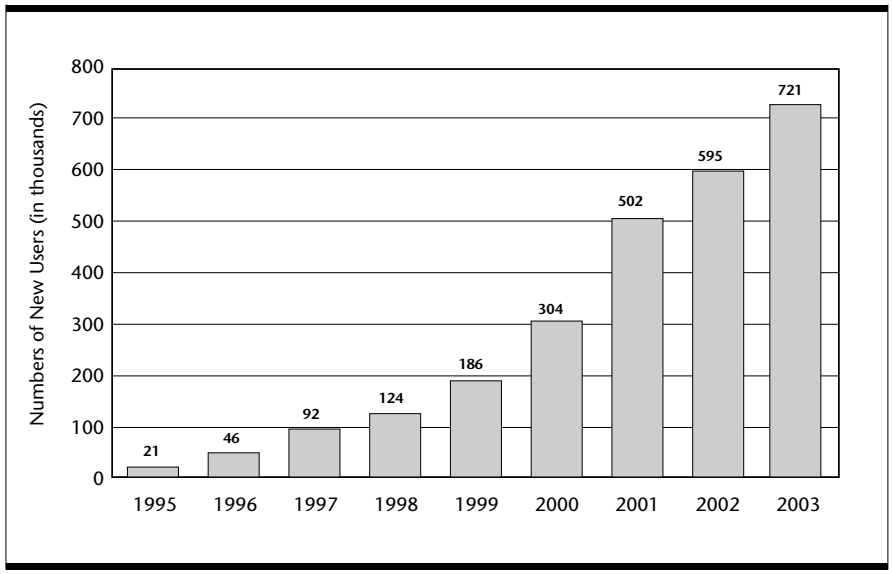
Figure 3.12: Past year initiates for illicit drug use, USA, 2004



Note: Sedatives refers to barbiturates.
Source: Substance Abuse and Mental Health Services Administration 2005, p.47.

Data from the NSDUH shows the growth in new non-medical users of OxyContin® since it was first introduced in 1995. These statistics are shown in Figure 3.13.

Figure 3.13: Trends in new non-medical users of OxyContin® in USA, 1995–2003



Source: Substance Abuse and Mental Health Services Administration 2005, p.50.

Although the Substance Abuse and Mental Health Services Administration does not report extensive analysis of trends in non-medical use of pharmaceutical drugs by drug type, it does provide lifetime use by age for specific tranquillisers and analgesics and these are provided below (Table 3.8 and Table 3.9 respectively). Thus Table 3.8 shows that some 1.8 per cent of Americans aged 12 years or over illicitly used benzodiazepines in 2004, and that use was highest in the 18–25-year-old age group. Diazepam was the most commonly misused benzodiazepine.

Table 3.8: Non-medical lifetime use of specific tranquillisers by age group, per cent of respondents, 2003 and 2004

	Age group							
	Total		12–17		18–25		26 or older	
Tranquilizer	2003	2004	2003	2004	2003	2004	2003	2004
Klonopin® or Clonazepam	1.2	1.1	0.6	0.7	3.0	3.3	1.0	0.8
Xanax®, Alprazolam, Ativan® or Lorazepam	4.0	3.9	1.7	1.8	7.5	7.7	3.7	3.5
Valium® or Diazepam	6.2	6.1	1.7	1.5	7.8	7.6	6.5	6.4
Atarax®	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
BuSpar®	0.2	0.3	0.2	0.2	0.6	0.8	0.2	0.2
Equanil®	0.1	0.0	0.1	0.0	0.0	0.1	0.1	0.0
Flexeril®	0.8	0.8	0.2	0.1	1.2	1.4	0.9	0.8
Librium®	0.5	0.4	0.1	0.1	0.3	0.2	0.6	0.5
Limbitrol®	0.0[a]	0.0	0.0	0.1	0.0	0.1	0.0	0.0
Meprobamate	0.1	0.1	0.0	0.1	0.0	0.0	0.1	0.1
Miltown®	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0
Rohypnol®	0.2	0.1	0.2	0.1	0.6	0.4	0.1	0.1
Serax®	0.1	0.0	0.0	0.0	0.1	0.1	0.1	0.0
Soma®	1.1	1.1	0.6	0.5	2.5[a]	3.0	0.9	0.8
Tranxene®	0.1	0.1	0.1	0.0	0.1	0.1	0.1	0.1
Vistaril®	0.1	0.1	0.0	0.1	0.1	0.2	0.1	0.1
Selected groups of drugs								
Benzodiazepines[1,2]	8.0	7.8	2.9	2.8	11.5	11.2	8.0	7.8
Meprobamate Products[1,3]	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Muscle Relaxants[1,4]	1.6	1.6	0.7	0.6	3.1[b]	3.8	1.4	1.4

Notes: a Difference between estmate and 2004 estimate is statistically significant at the 0.05 level.
b Difference between estmate and 2004 estimate is statistically significant at the 0.01 level.
1 Includes other specify drug responses that are not asked about explicitly in the Tranquilizers module but fall into this category.
2 Includes Klonopin® or clonazepam, Xanax®, alprazolam, Ativan® or lorazepam, Valium® or diazepam, Librium®, Limbitrol®, Rohypnol®, Serax®, and Tranxene®.
3 Includes Equanil®, meprobamate, and Miltown®.
4 Includes Flexeril® and Soma®.

Source: Substance Abuse and Mental Health Services Administration 2005, p.243.

Table 3.9 shows that in 2004 analgesics in the propoxyphene or codeine group were most often misused (9.8%), followed by hydrocodone (7.4%) and oxycodone (5.0%) products. As with the benzodiazepines, use was highest in the 18–25 year-old-group, and there were significant increases over the last two surveys in use of both oxycodone and hydrocodone products in this age group.

Table 3.9: Non-medical lifetime use of specific analgesics by age group, per cent of respondent, 2003 and 2004

	Total		Age group 12–17		18–25		26 or older	
Pain Reliever	2003	2004	2003	2004	2003	2004	2003	2004
Darvocet®, Darvon®, or Tylenol® with Codeine	8.3	8.1	5.8	6.0	12.7	13.1	7.8	7.5
Percocet®, Percodan®, or Tylox®	4.5	4.6	1.9	2.1	7.8[a]	8.7	4.3	4.2
Vicodin®, Lortab®, or Lorcet®	6.6	6.9	4.5[a]	5.1	15.0[b]	16.5	5.4	5.5
Codeine	2.9	2.8	2.1	2.1	6.5	6.4	2.4	2.2
Demerol®	1.3[b]	1.0	0.4	0.5	2.2	1.9	1.2[b]	0.9
Dilaudid®	0.4	0.4	0.1	0.1	0.3	0.3	0.5	0.4
Fioricet®	0.2	0.2	0.1	0.1	0.2	0.2	0.2	0.2
Fiorinal®	0.2	0.2	0.1	0.0	0.1	0.1	0.3	0.2
Hydrocodone	2.4	2.5	1.6	1.7	6.6	6.7	1.8	1.8
Methadone	0.5	0.5	0.4	0.5	1.2	1.4	0.4	0.4
Morphine	0.9	0.9	0.9	0.9	2.3	2.5	0.6	0.6
OxyContin®	1.2	1.3	1.0	1.2	3.6[a]	4.3	0.8	0.8
Phenaphen® with Codeine	0.4[b]	0.2	0.3[a]	0.2	0.7	0.6	0.3[a]	0.2
Proxyphene	0.1	0.2	0.1	0.1	0.2	0.3	0.1	0.1
SK-65®	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0
Stadol®	0.1	0.1	0.0	0.0	0.1[b]	0.2	0.1	0.1
Talacen®	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0
Talwin®	0.2	0.1	0.0	0.1	0.1	0.1	0.2	0.1
Talwin® NX	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Tramadol	0.1[a]	0.1	0.1	0.1	0.2	0.3	0.1	0.1
Ultram®	0.5	0.5	0.3	0.2	1.0	1.0	0.4	0.4
Selected groups of drugs								
Propoxyphene or Codeine Products[1,2]	9.0	8.8	6.8	6.7	14.5	14.6	8.4	8.0
Oxycodone Products[1,3]	4.9	5.0	2.4	2.7	8.9[b]	10.1	4.5	4.4
Hydrocodone Products[1,4]	7.1	7.4	5.0	5.6	16.3[a]	17.4	5.7	5.9
Tramadol Products[1,5]	0.5	0.5	0.3	0.3	1.2	1.2	0.4	0.5

Notes: a Difference between estmate and 2004 estimate is statistically significant at the 0.05 level.
b Difference between estmate and 2004 estimate is statistically significant at the 0.01 level.
1 Includes other-specify drug responses that are not asked about explicitly in the Pain Relievers module but fall into this category.
2 Includes Darvocet®, Darvon® or Tylenol® with Codeine, Phenaphen® with Codeine, proxyphene, and SK-65®.
3 Includes Percocet®, Percodan® or Tylex®, and OxyContin®.
4 Includes Vicodin®, Lortrab®, or Lorcet®, and hyrdocodone.
5 Includes tramadol and Ultram.

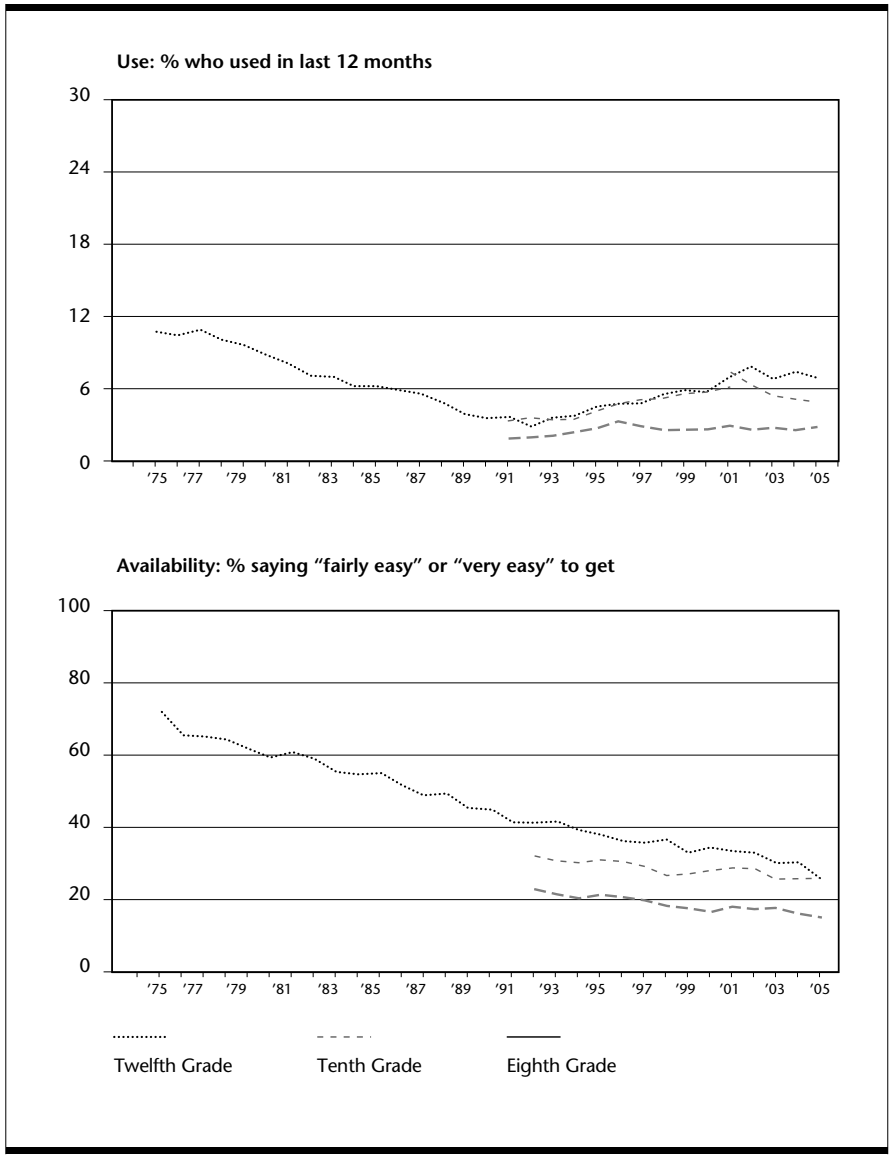
Source: Substance Abuse and Mental Health Services Administration 2005, p.242.

Monitoring the Future Study

In the 2005 the Monitoring the Future Study (Johnston, O'Malley et al. 2006), approximately 49,300 United States secondary school students were surveyed. In 2005, approximately 7 per cent of students in Grade 12, 5 per cent of Grade 10 students and 3 per cent of Grade 8 students had consumed tranquillisers for non-medical purposes in the previous year. Long-term trends in tranquilliser use presented in Figure 3.14 show a 75 per cent decline in use between the late 1970s and 1992. Their use increased during the 1990s before reaching a plateau in 2002. Perceived availability, as measured by the proportion of respondents

saying that it would be 'fairly easy' or 'very easy' to obtain tranquillisers if they wanted them, fell from 72 per cent in 1975 to 26 per cent in 2005. This data is also presented in 3.14.

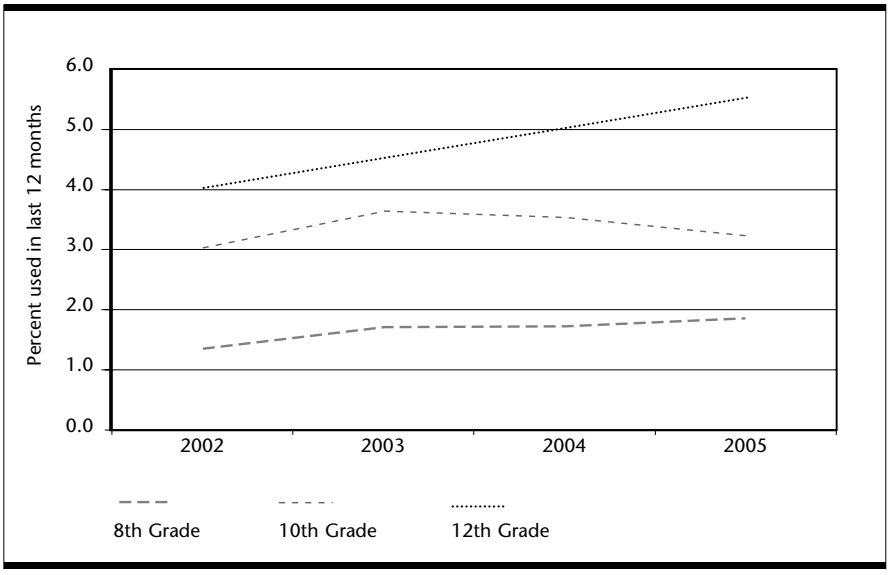
Figure 3.14: Recent use and availability of tranquillisers, secondary students, USA, 1975 to 2005



Source: Johnston, O'Malley, Bachman & Schulenberg 2006, p.29.

Rates of OxyContin® use have been measured since 2002 and have risen steadily among Grade 12 students but not among Grade 8 or Grade 10 students. Thus in 2003, 3.5 per cent of the older students had used OxyContin®, a 40 per cent increase since 2002. These data are presented in Figure 3.15.

Figure 3.15: OxyContin® use in last 12 months by students in grades 8, 10 and 12, USA, 2002–2005



Source: Data extracted from Johnston, O'Malley, Bachman & Schulenberg 2006.

United Kingdom data

As noted above, due to the United Kingdom drug classification system and the way the British Crime Survey is conducted and reported, it is only possible to extract estimates of illicit use for methadone and 'tranquillisers' (barbiturates and benzodiazepines combined). In 2003/04 an estimated 955,000 (3.1%) 16- to 59-year-olds in England and Wales had ever used tranquillisers illicitly; 186,000 (0.6%) had done so in the preceding year and 69,000 (0.2%) had used them illicitly in the month prior to interview. With regards to methadone, 115,000 (0.4%) individuals aged 16 to 59 years had ever illicitly used the drug; 25, 000 (0.1%) had done so in the past year and 15,000 (<0.1%) in the past month. Among those aged 16 to 24, it was estimated that 166,000 (2.8%) in 2003/04 had ever used tranquillisers illicitly; 50,000 (0.8%) had done so in the preceding year and 20,000 (0.3%) had used them illicitly in the month prior to interview. With regards to methadone 41,000 (0.7%) 16- to 24-year-olds had ever used the drug illicitly; 14,000 (0.2%) had done so in the past year and 6,000 (0.1%) in the past month (data extracted from Chivite-Matthews et al. 2005).

The Australian situation

National Drug Strategy Household Survey (NDSHS)

Data from the 2004 National Drug Strategy Household Survey presented in Table 3.10 indicate that 7.6 per cent of Australians, (1,026,300 individuals) 14 years and over, had used pharmaceutical drugs (pain killers, tranquillisers, barbiturates or steroids) for non-medical purposes at least once in their lives; 3.8 per cent in the past year (658,300 individuals) and 2 per cent in the past

month (259,400). Males (8.2%) were more likely than females (7.0%) to have ever used these drugs, but roughly equal proportions of males (3.6%) and females (3.9%) had used them illicitly in the past 12 months. Those Australians 20 to 29 years of age were most likely to have used these drugs for non-medical purposes in their lifetime, and in the past 12 months or the last month (AIHW 2005a).

Table 3.10: Use of pharmaceuticals for non-medical purposes by persons aged 14 years and older, by age and sex, Australia, 2004

	Age group				Sex		
Period	14–19	20–29	30–39	40+	Males	Females	Persons
				(per cent)			
In lifetime	6.3	10.8	9.0	6.4	8.2	7.0	7.6
In the last 12 months	4.0	5.1	3.9	3.3	3.6	3.9	3.8
In the last month	1.5	2.4	2.0	2.0	1.9	2.2	2.0
In the last week	0.8	1.2	1.2	1.2	1.1	1.3	1.2
				(number)			
In lifetime	103,900	172,900	186300	563,200	506,300	520,000	1,026,300,
In the last 12 months	66,600	110,900	119,500	361,200	324,500	333,500	656,300
In the last month	26,300	43,700	47,100	142,400	126,000	131,400	259,400
In the last week	14,000	23,400	25,200	75,100	68,400	70,300	138,700

Source: Australian Institute of Health and Welfare (AIHW) 2005a, p.47.

Table 3.11 shows use of pharmaceuticals in the previous 12 months by age and drug type. It indicates that analgesics were the most common pharmaceutical used for illicit purposes with 3.1 per cent of Australians having done so in the past year, followed by tranquillisers or sleeping pills used by 1.0 per cent in that period. Australians aged 20 to 29 years were most likely to have used analgesics or tranquillisers for non-medical purposes in the past 12 months (AIHW 2005a).

Table 3.11: Last 12 months use of selected pharmaceuticals by persons aged 14 years and older, by age and sex, Australia, 2004

	Age group				
Pharmaceuticals	**14–19**	**20–29**	**30–39**	**40+**	**Aged 14+**
Males					
Pain killers/analgesics	1.9	4.1	2.6	2.8	2.9
Tranquilisers/sleeping pills	0.9	2.3	1.2	0.6	1.1
Steroids	0.1*	0.1*	0.2*	—*	0.1*
Barbiturates	0.4*	0.5	0.3*	0.1*	0.2
Females					
Pain killers/analgesics	4.2	3.5	3.6	2.9	3.3
Tranquilisers/sleeping pills	1.3	1.9	1.1	0.7	1.0
Steroids	—*	—*	—*	—*	—*
Barbiturates	0.5*	0.1*	0.2*	—*	0.1
Persons					
Pain killers/analgesics	3.1	3.8	3.1	2.9	3.1
Tranquilisers/sleeping pills	1.1	2.1	1.2	0.6	1.0
Steroids	0.1*	—*	0.1*	—*	—
Barbiturates	0.5	0.3	0.2	—*	0.2

Note: * Figures unreliable as relative standard error is greater than 50%.
Source: Australian Institute of Health and Welfare (AIHW) 2005a, p.48.

Table 3.12 shows that among those who had used pharmaceutical drugs for non-medical purposes in the past 12 months, approximately one in four did this on a daily basis (AIHW 2005a).

Table 3.12: Frequency of non-medical use of pharmaceuticals in last 12 months by persons aged 14 years and older, by age and sex, Australia, 2004

	Age Group				Sex		
	14–19	**20–29**	**30–39**	**40+**	**Males**	**Females**	**Persons**
				(per cent)			
Daily or weekly	10.9*	16.1	23.2	33.4	23.2	26.2	24.8
About once a month	24.5	24.6	25.7	20.0	19.9	25.3	22.7
Every few months	29.5	20.9	18.1	23.2	20.8	23.8	22.4
Once or twice a year	34.8	38.4	33.8	23.3	36.1	27.7	

Notes: 1. Base is recent users.
2. * Figures unreliable as relative standard error is greater than 50%.
Source: Australian Institute of Health and Welfare (AIHW) 2005a, p.49.

Drug Use Monitoring (DUMA) data

With regards to the use of pharmaceutical drugs among persons incarcerated by police or correctional services in Australia, some figures are provided by the DUMA project. DUMA data is collected from detainees on a quarterly basis from seven police stations or watchhouses around Australia. From the most recent DUMA report in which 3,834 detainees were interviewed, positive tests for benzodiazepines were recorded among 20 per cent of males and 36 per cent

of females. However, because benzodiazepines can be detected in urine up to 14 days after use, and because they can be prescribed licitly, DUMA also inquires about non-medical use (not prescribed by a doctor or other health professional and not due to over-the-counter medications). Some 17 per cent of females and 11 per cent of male detainees said that they had taken prescription benzodiazepines during the previous two weeks and 28 per cent of these said they had also used these drugs illegally over the past month (Schulte, Mouzos & Makkai 2005).

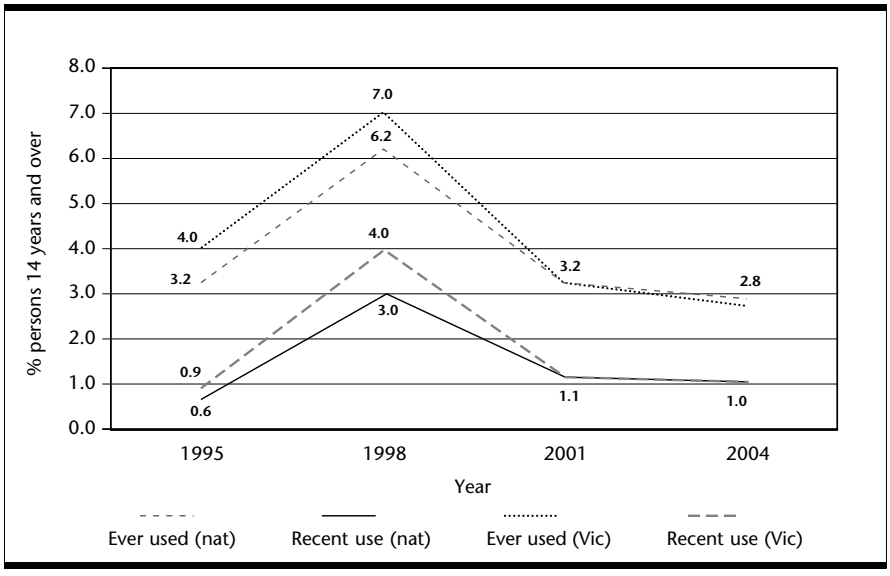
There were 583 positive tests for opiate metabolites of which 21 per cent were unlikely to have been derived from heroin, although the licit or illicit origins of these opiates could not be determined. The report noted that the proportions testing positive for opiate metabolites unlikely to have been derived from heroin has been increasing in recent years from 10 per cent in 2000, to 18 per cent in 2001 and 23 per cent in 2002 and 2003 (Schulte, Mouzos & Makkai 2005).

Comparing Victorian and national data

National Drug Strategy Household Survey

An analysis of NDSHS data on non-medical benzodiazepine use from 1995 to 2004 indicates that both nationally and in Victoria use was highest in 1998 and has declined since. This data is presented in Figure 3.16. The similarity between rates of non-medical use of benzodiazepines in Victoria and nationally is evident.

Figure 3.16: Rates of lifetime (ever) and recent (last 12 months) use of benzodiazepines for non-medical purposes, 1995–2004

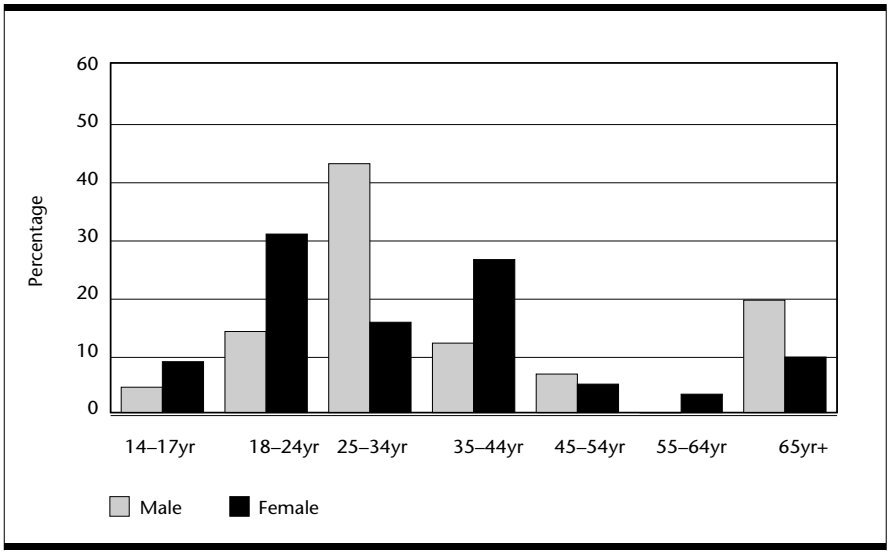


Source: Data from Department of Human Services (DHS) Victoria 2006e; Australian Institute of Health and Welfare (AIHW) 1999, 2002, 2005a.

An analysis of 2004 NDSHS data found that 43 per cent of Victorian males aged between 25 and 34 reported use of benzodiazepines for non-medical purposes

in the previous 12 months compared to 16 per cent of females, thus reversing the typical gender use pattern for other age groups (DHS Victoria 2006e). Figure 3.17 shows the percentages of such use and age and sex of users.

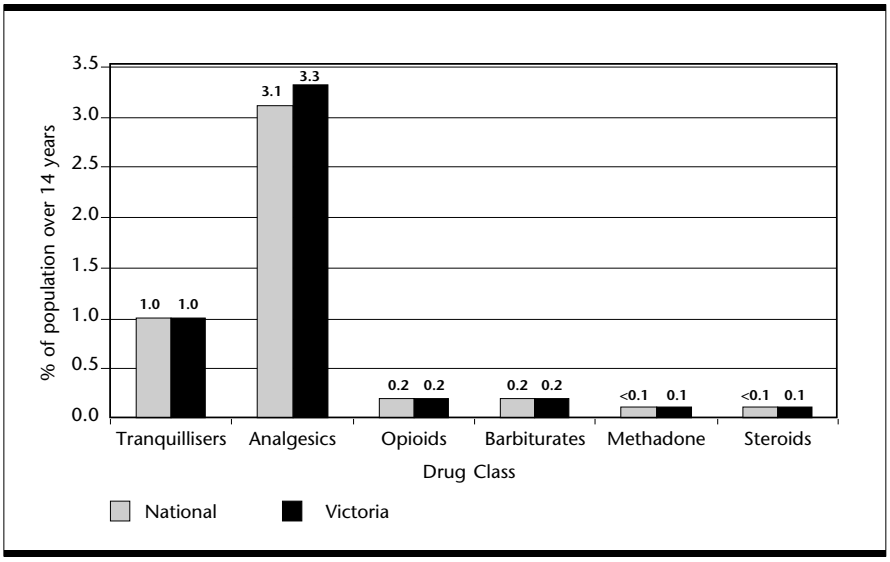
Figure 3.17: Prevalence estimates of last 12 months non-medical use of tranquillisers by age and sex, Victoria, 2004



Source: Department of Human Services (DHS) Victoria 2006e, p.57.

The NDSHS also examines, across the states and territories, the non-medical use of a number of other classes of pharmaceutical drugs in addition to benzodiazepines. Data from the 2004 survey indicates that, except for analgesics, rates of non-medical use of these pharmaceutical drugs in the previous 12 months remains relatively low at 0.2 per cent or less among persons aged 14 years and over. Overall, Victorian rates of non-medical use of these drugs in the last 12 months are similar to the national figures, although 3.3 per cent of Victorians reported recent non-medical use of analgesics compared with 3.1 per cent nationally (AIHW 2005c). This data is presented in Figure 3.18 below.

Figure 3.18: Last 12 months non-medical use of pharmaceutical drugs in Victoria and nationally



Source: Data from Australian Institute of Health and Welfare (AIHW) 2005c.

Calls to DirectLine

Table 3.13 shows the number of calls received by DirectLine between 1999 and 2004 where benzodiazepines and other tranquillisers were cited as the drugs of concern.[53] Over this period a total of 7,682 calls relating to benzodiazepines and/or other major tranquillisers were received, representing an average of 2.4 per cent of all calls received by the service. The majority of callers were female, with 60 per cent of calls relating to personal use and 74 per cent relating to the use of benzodiazepines and/or other major tranquillisers by others. The number of calls relating to the use of benzodiazepines and/or other major tranquillisers has remained relatively constant since 1999 although a peak in calls was apparent during 2001 and 2002 (DHS Victoria 2006e).

53 Data were limited to valid DirectLine calls by removing all administrative, hoax, immediate hang up or wrong number calls. HealthLink manages several addiction-related health information and referral telephone support services in Victoria and for other states or territories and calls for these services were also excluded from analysis (DHS Victoria 2006e).

Table 3.13: Number of calls received by DirectLine between 1999 and 2004 where benzodiazepines and other tranquillisers were cited as the drugs of concern

Year	Total number of calls to DL	Total calls drug-identified	Benzodiazepines and/or other major tranquillisers a drug of concern	% of drug-identified	% of all callsTotal calls drug-identified
1999	39,284	21,351	1,216	5.7%	3.1%
1999	39,440	19,746	1,087	5.5%	2.8%
2001	41,159	20,922	1,461	7.0%	3.6%
2002	45,307	24,990	1,341	5.4%	3.0%
2003	48,151	24.861	1,372	5.5%	2.9%
2004	48,776	26,990	1,205	5.4%	2.5%

Source: Department of Human Services (DHS) Victoria 2006e, p.59.

Table 3.14 shows that 7,798 calls were made to DirectLine in 2004 identifying 'other opioids' (comprising 76 per cent methadone calls and 22 per cent buprenorphine) as the primary drugs of concern. Although methadone and buprenorphine related calls might relate to licit use, this was a 12 per cent increase in 'other opioid' calls from 2003 and a continuation of substantial increases since 2001. Calls where 'other opioids' were identified as the primary drugs of concern represented 29 per cent of all drug-identified calls and 16 per cent of all calls to DirectLine in 2004. These proportions have increased considerably since 2001. It should be noted that in 2004 heroin accounted for only 7 per cent of all calls made to DirectLine. In 2004 buprenorphine was identified in 1,711 'other opiates' calls comprising a 6 per cent increase on 2003. Buprenorphine represented 6 per cent of drug-identified calls and 4 per cent of all calls to DirectLine in 2004. There has been a steady increase in buprenorphine-related calls since it was made available on the PBS in August 2001 (DHS Victoria 2006e).

Table 3.14: Number of calls to DirectLine where opioids were cited as drugs of concern, Victoria, 1999–2004

Year	Total number of calls to DL	Total calls drug-identified	Other opioids a drug of concern	% of drug-identified	% of all calls
1999	39,284	21,351	3,690	17.28%	9.39%
2000	39,440	19,746	4,019	20.35%	10.19%
2001	41,159	20,922	3,839	18.35%	9.33%
2002	45,307	24,990	6,214	24.87%	13.72%
2003	48,151	24.861	6,950	27,96%	14.43%
2004	48,776	26,990	7,798	28.89%	15.99%

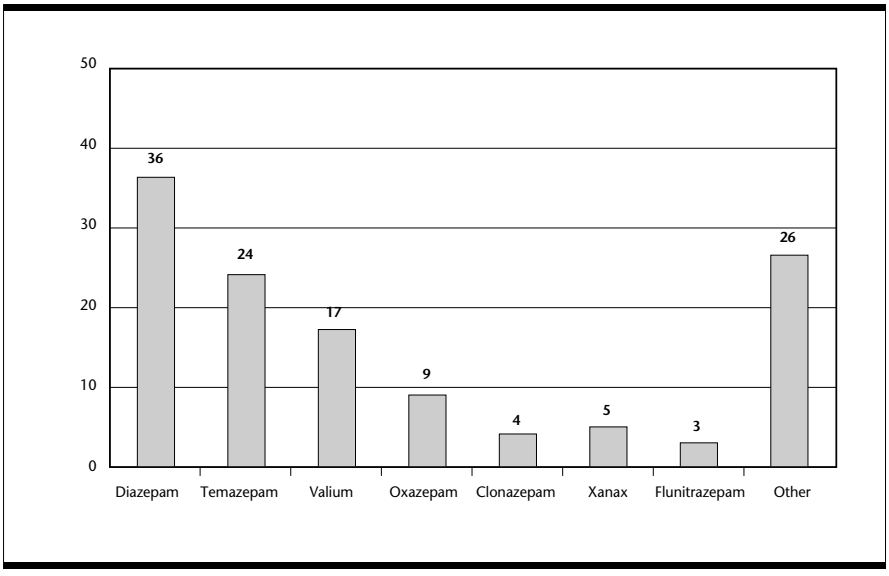
Note: This table referred originally to 'other opiates', but should use the term 'other opioids'.
Source: Department of Human Services (DHS) Victoria 2006e, p.81.

Victorian Youth Alcohol and Drugs Survey

> Teen prescription drug abusers represent an especially vulnerable group. Teens may view prescription drugs as relatively safe either when abused alone or in combination with alcohol or other drugs and, for them, prescription drugs may serve as gateway drugs to other substances of abuse. In addition to teen abuse of these drugs for purposes of partying or studying, some teens abuse prescription drugs to self-medicate feelings of stress or depression, anxiety or other mental health problems that may go undetected or untreated by the adults around them (CASA 2005, p.4).

Overall, 3 per cent of young Victorians aged 16 to 24 years of age surveyed in the Victorian Youth Alcohol and Drugs Survey in 2004 reported ever using tranquillisers for non-medical purposes and 2 per cent had done so in the last 12 months. There was a slight decrease on the lifetime use figure of 4 per cent obtained in 2003 and this this appeared to be due to a fall in lifetime use by females. Since the 2003 survey there has been no change in recent use. As shown in Figure 3.19, diazepam, temazepam, Valium® (which is diazepam) and oxazepam were the benzodiazepines most used by young Victorians for non-medical purposes in 2004 (Premier's Drug Prevention Council 2005).

Figure 3.19: Types of benzodiazepines used by Victorians aged 16–24 for non-medical purposes during the previous 12 months, 2004 – per cent of respondents (n=110)



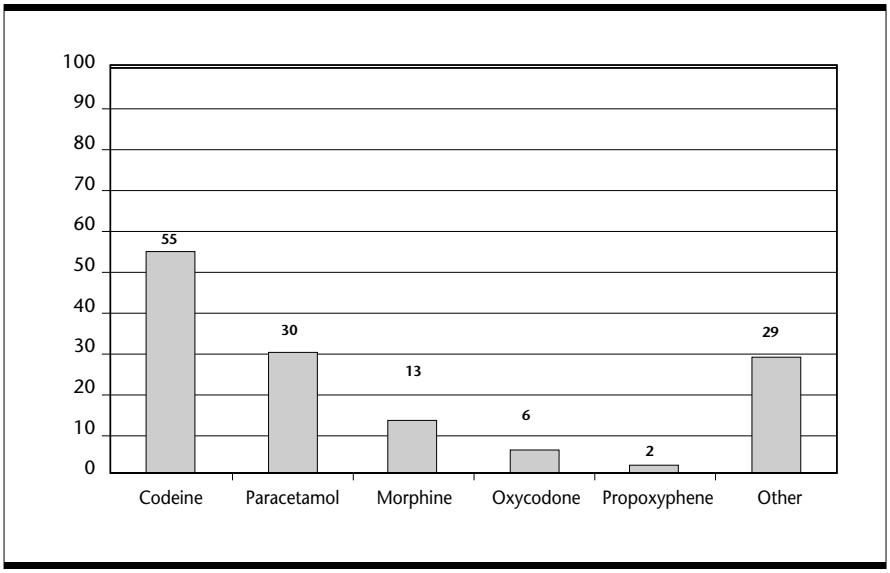
Note: This Table depicts both generic and trade name drugs, for example Valium is the trade name for diazepam and Xanax is the trade name for alprazolam.

Source: Premier's Drug Prevention Council 2005, p.21.

As in 2002 and 2003, 4 per cent of 16- to 24-year old Victorians surveyed in 2004 reported ever using analgesics for non-medical purposes and 2 per cent of these had used in the last 12 months. There were little differences between males and

females. The most frequent analgesic drugs used by this group in 2004 are presented in Figure 3.20.

Figure 3.20: Types of analgesics used for non-medical purposes by Victorians aged 16–24 during the previous 12 months, 2004 – per cent of respondents (n=110)



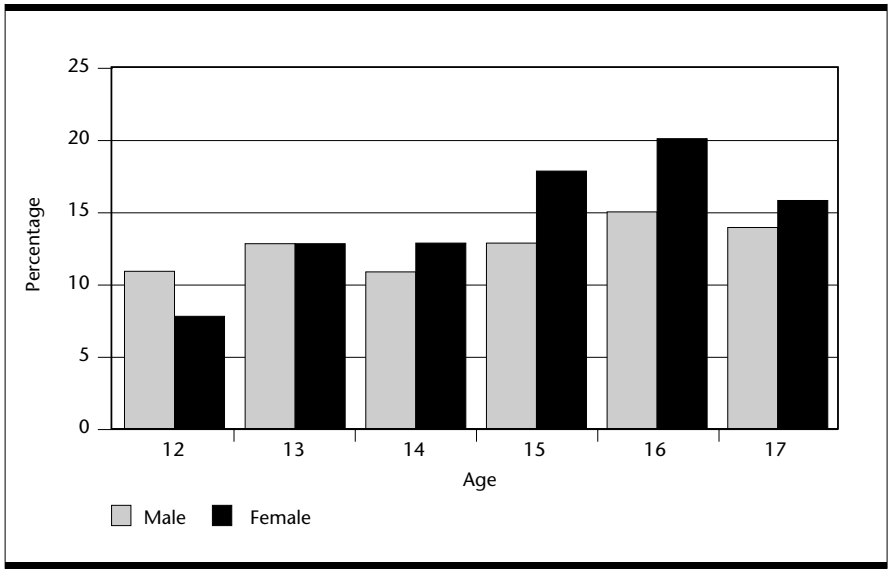
Source: Premier's Drug Prevention Council 2005, p.20.

The Australian Secondary Students' Alcohol and Drug (ASSAD) survey

Although the ASSAD survey reports on a range of drugs including tranquillisers and 'pain killers', questions regarding the latter class do not distinguish between the type of medicine (over-the-counter vs. prescription) or whether they have been taken for medical or non-medical reasons. As a consequence, the data on analgesics from this survey is of limited use in the current Inquiry, as almost all students have used some painkillers at least once recently.

However, the data on tranquilliser use is useful as it refers to non-medical use. Victorian data from the 2002 ASSAD survey indicate that use of benzodiazepines for non-medical purposes occurred at a higher rate (13% of males and 14% of females) than for most illicit drugs. Data on lifetime use by age and sex is presented in Figure 3.21. It shows rates of use were higher among females in each age group from age 14 and over (DHS Victoria 2004).

Figure 3.21: Lifetime use of tranquillisers, Victorian students aged 12 to 17, 2002



Source: Department of Human Services (DHS) Victoria 2004, p.90.

Table 3.15 presents the percentage of Victorian students who reported that they had ever used tranquillisers other than for medical reasons, across the previous three years of the ASSAD survey: 1996, 1999 and 2002. Overall, there was no significant change in lifetime use of tranquillisers across the survey years. However, the decrease in use for 12- to 15-year-old students was statistically significant, with fewer students (13%) reporting tranquilliser use in 2002 than in 1996 (18%). There was also a significant decrease in past months use by 12- to 15-years-olds (from 4% in 1996 and 1992 to 3% in 2002) and 16- to 17-years-olds (from 5% in 1996 and 1992 to 4% in 2002) (DHS Victoria 2004).

Table 3.15: Trends in the lifetime use of tranquillisers by Victorian students by gender and age, 1996–2002

	12 to 15-year-olds			16 to 17-year-olds		
	1996	1999	2002	1996	1999	2002
Sedatives Lifetime Lifetime						
Male (%)	17*	17*	12	18	20	15
Female (%)	19	13	13	19	20	18
Total (%)	18*	15	13	19	20	16

Note: * Significantly different from 2002 at p<01 level.
Source: Department of Human Services (DHS) Victoria 2004, p.91.

The Illicit Drug Reporting System (IDRS)

The latest data from the IDRS, which includes surveys with injecting drug users in each Australian state and territory on a national basis, indicates that

significant proportions of the sample had used pharmaceutical drugs illicitly over the previous six months.

Table 3.16 presents data on selected pharmaceutical drugs used by injecting drug users in the six months prior to interviews conducted as part of the IDRS during 2005. The data shows that larger proportions of the Victorian injecting drug users, compared to the national average, had used buprenorphine either licitly or illicitly in that year. This may reflect the widespread licit use of buprenorphine to treat opiate dependence in Victoria. This is elaborated on in data presented below. It can be seen that in the Northern Territory and Tasmania rates of illicit use of morphine and methadone are higher than in other jurisdictions. This phenomenon is common where heroin is less available on the illicit market, as is the case in those two jurisdictions. This issue is discussed further in Chapter 5.

Table 3.16: Selected pharmaceutical drugs used by injecting drug users in the preceding six months by state and territory, 2005

Form	NSW	ACT	Tas	SA	WA	NT	Qld	Vic	National
Methadone liquid									
licit %	55	46	45	28	22	18	25	27	35
illicit[1] %	17	27	52	24	24	21	21	9	24
Methadone Tablets									
licit %	3	4	7	1	1	6	0	1	3
illicit %	3	6	41	13	8	32	3	1	12
Buprenorphine[2]									
licit %	25	19	8	27	25	11	11	49	23
illicit %	8	16	5	14	34	20	19	31	18
Morphine									
licit %	5	9	3	10	6	30	4	6	44*
illicit %	24	30	58	31	49	70	33	37	
Oxycodone									
licit	3	7	3	7	6	1	6	3	5
illicit	14	12	30	11	39	11	15	16	18
Benzodiazepines									
licit %	41	42	55	44	54	27	34	48	66*
illicit %	40	32	66	28	39	34	34	49	
Anti-depressants									
licit %	23	18	29	21	24	22	17	29	25*
illicit %	0	3	5	10	3	3	4	2	

Note: * National figures for use in the past six months for morphine and benzodiazepines and anti-depressant do not distinguish between illicit and licit.

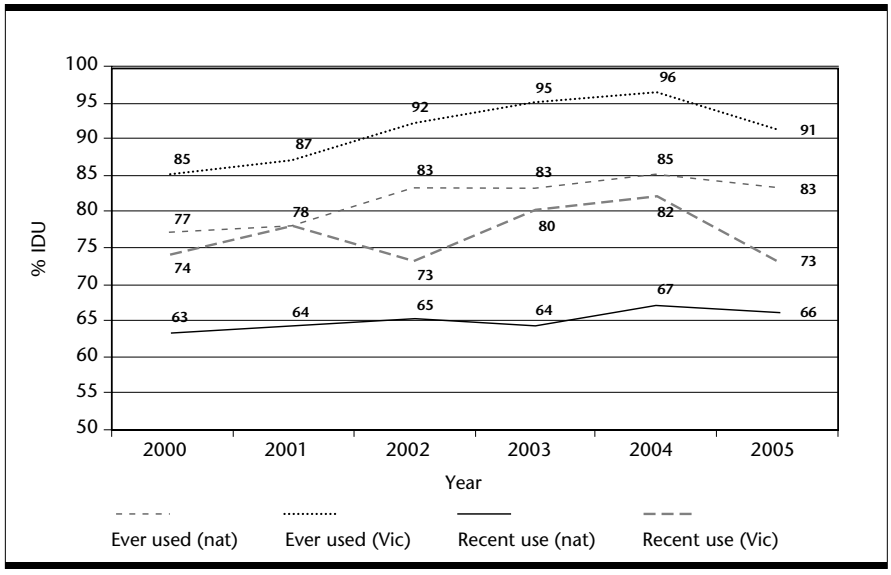
Source: Stafford, Degenhardt, Black et al. 2006, pp.20–21.

Benzodiazepines

As the above Table shows, some 66 per cent of the national sample reported using benzodiazepines in the previous six months; 43 per cent licitly and 40 per cent illicitly. Eight per cent reported injection of benzodiazepines in the past six months. Some 73 per cent of the Victorian sample reported using

benzodiazepines in the previous six months, 47 per cent reported using prescribed benzodiazepines and 49 per cent illicitly obtained ones. The types most commonly used were diazepam (eg. Valium®) (62%); oxazepam (eg. Serepax®) (16%); and alprazolam (eg. Xanax®) (8%) (Jenkinson & O'Keefe 2006). Figure 3.22 shows that Victorian rates of ever and recent (last 6 months) use of benzodiazepines have been higher than the national rates but have decreased in the 2005 survey to a greater extent than the national figures.

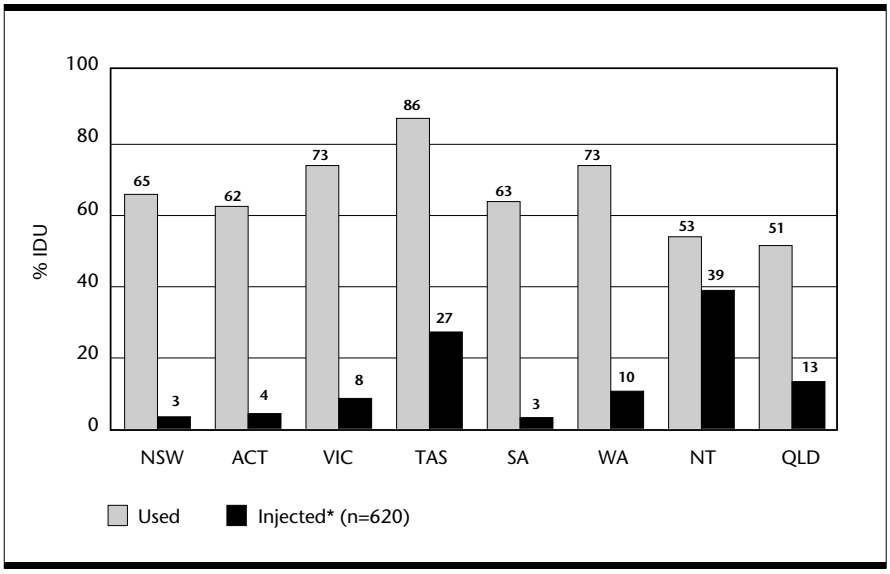
Figure 3.22: Victorian and national rates of illicit benzodiazepine use among IDRS interviewees 2000–2005



Source: Data extracted from Jenkinson & O'Keefe 2006; Stafford, Degenhardt, Black et al. 2006.

Although in 2005 rates of recent (last 6 months) benzodiazepine use in Victoria remained higher than the national average, one can see that in Figure 3.23 Victoria is not the jurisdiction with the highest rates of recent use or injection.

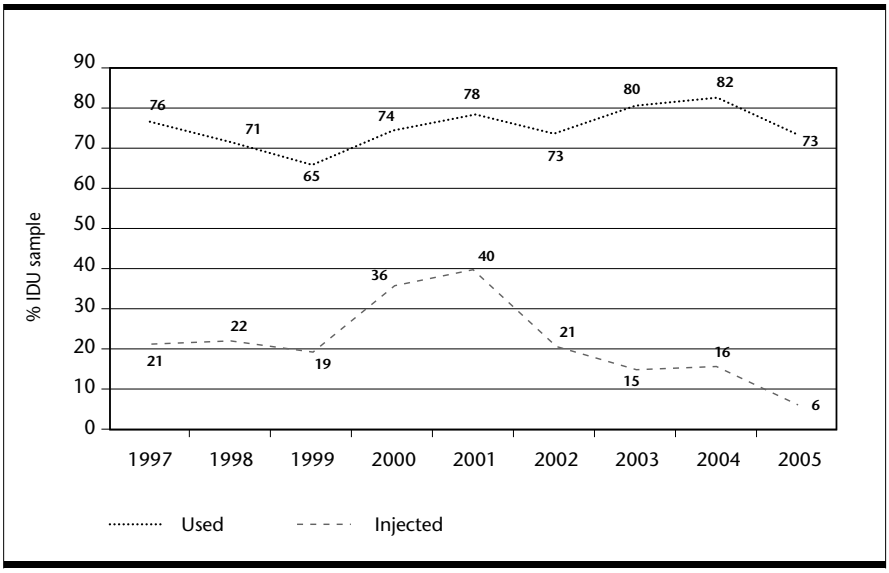
Figure 3.23: Proportion of injecting drug users that reported use and injection of benzodiazepines in the previous six months, by jurisdiction



Note: * among those who reported recent use (n=620)
Source: Stafford, Degenhardt, Black et al. 2006, p.126.

Importantly, trend data on the proportion of Victorian injectors interviewed as part of the IDRS over the period 1997 to 2001 show that while the proportion injecting benzodiazepines increased up until 2001, this proportion decreased after the changes made to the PBS prescribing authority for temazepam in May 2002. Indeed, in 2005 the reported rates of injecting were lowest reported in Victoria since the IDRS commenced (Jenkinson & O'Keefe 2006). Jenkinson and O'Keefe also note that the DHS Victoria's Temazepam Injection Prevention Initiative was implemented in November 2001, and in March 2004 gel-cap temazepam formulations were withdrawn from the market. Trends in use and injection of benzodiazepines in Victoria and nationally are presented in Figure 3.24 and Table 3.17.

Figure 3.24: Trends in proportion of Victorian injecting drug users reporting use and injection of benzodiazepines in the previous six months, 1997–2005



Source: Jenkinson & O'Keefe 2006, p.55.

Table 3.17: Injection of benzodiazepines in previous six months, 1999–2005

	1999	2000	2001	2002	2003	2004	2005
National %	14	21	24	21	17	14	8
Victoria %	19	36	40	21	15	16	6

Source: Data extracted from Stafford, Degenhardt, Black et al. 2006; Topp, Darke et al. 2001.

Methadone

Table 3.16 shows that nationally, 24 per cent of the IDRS sample reported use of illicit methadone syrup, and 12 per cent the illegal use of methadone tablets (Physeptone®) in the six months prior to their interview. Some 26 per cent of those who reported use of methadone in the previous six months said illicit methadone was the most frequent form they had used. Among the Victorian sample some 9 per cent reported use of illicit methadone syrup in the previous six months and only 1 per cent reported use of illicit Physeptone® over that period. Only 3 per cent of Victorian respondents reported injection of methadone in the previous six months.

Table 3.18 shows trends since 2003 in use of licit and illicit methadone in the previous six months for the national and Victorian IDRS samples. Prior to 2003 no distinction was made in the IDRS between licit and illicit methadone use, so figures in this Table for the years 2000–2002 show only the total percentage of users.

Table 3.18: Licit and illicit use of methadone in the previous six months among national and Victorian IDRS samples, 2000–2005

	2000*	2001*	2002*	2003	2004	2005
National %	44	48	44	49	50	52
				licit 33	licit 33	licit 35
				illicit 20	illicit 25	illicit 24
Victoria %	38	44	27	31	29	34
				licit 24	licit 21	licit 21
				illicit 12	illicit 10	illicit 10

Note: * No distinction was made between prescribed and illicit methadone until 2003.
Source: Data extracted from Illicit Drug Reporting System (IDRS) 2001, 2002, 2003, 2004, 2005, 2006, and R Jenkinson (personal communication) 14 July 2006.

Buprenorphine

Nationally, some 18 per cent of the 2005 national IDRS sample used illicit buprenorphine in the six months prior to interview. While Victoria had the largest proportion using licit buprenorphine in 2005 at 49 per cent, the state with the largest proportion of illicit use of the drug in the previous six months was Western Australia (34%) with Victoria second (31%) (Stafford, Degenhardt, Black et al. 2006). National and Victorian trends in licit and illicit buprenorphine use are presented in Table 3.19 below which shows a reduction in the ratio of illicit to licit buprenorphine by IDRS interviewees in Victoria.

Table 3.19: Licit and illicit use of buprenorphine in the previous six months among national and Victorian IDRS samples, 2002–2004

	2002	2003	2004	2005
National %	21	25	33	35
		licit 18	licit 21	licit 23
		illicit 12	illicit 16	illicit 18
Victoria %	53	53	59	63
		licit 38	licit 35	licit 49
		illicit 32	illicit 35	illicit 31

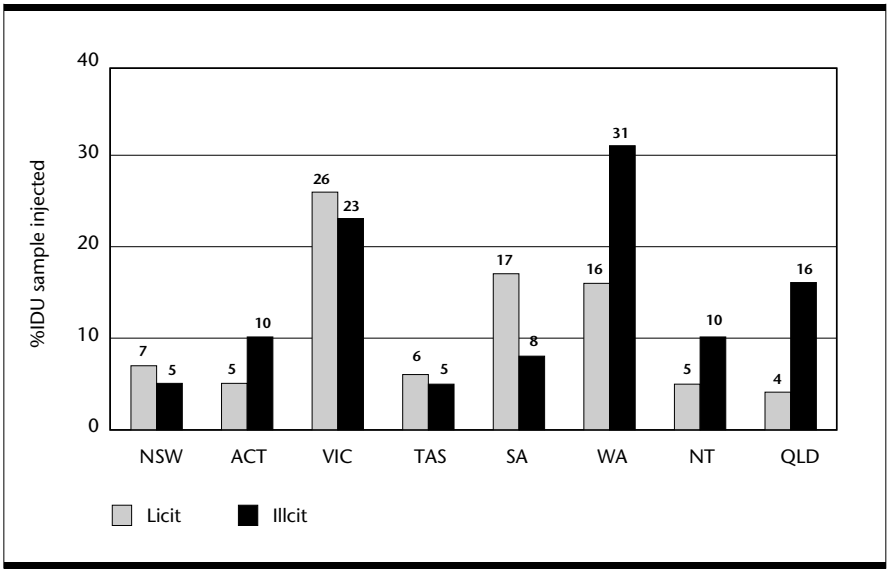
Note: Buprenorphine was measured for the first time in 2002 and illicit and licit use separated from 2003
Source: Data extracted from Illicit Drug Reporting System (IDRS) 2003, 2004, 2005, 2006; Jenkinson & O'Keefe 2005, 2006; Jenkinson, Miller & Fry 2004; R Jenkinson (personal communication) 14 July 2006; E Black (personal communication) 21 July 2006.

There is a great deal of concern about the injection of buprenorphine, which is manufactured to be taken sublingually (under the tongue) and is known to be responsible for significant vein damage and ulceration when injected.[54] Figure 3.25 below shows that there was considerable variation between jurisdictions

54 For further discussion of these types of harms see Chapter 4 of this Interim Report.

with regards to injection of buprenorphine. Large proportions of Victorian injecting drug users interviewed as part of the IDRS reported injection of buprenorphine prescribed to themselves (26%) or others (23%) (Stafford, Degenhardt, Black et al. 2006).

Figure 3.25: Proportion of injecting drug users that reported use and injection of buprenorphine in the previous six months, by jurisdiction, 2005



Source: Stafford, Degenhardt, Black et al. 2006, p.113.

National and Victorian trends in licit and illicit buprenorphine injecting by injecting drug users interviewed as part of the IDRS are presented in Table 3.20 below. Over the last four years rates of buprenorphine injection have increased both in Victoria and nationally.

Table 3.20: Injection of buprenorphine in last six months among national and Victorian IDRS samples, 2002–2005

	2002	2003	2004	2005
National %	8	9	12	21
				licit 11
				illicit 14
Victoria %	33	30	29	39
				licit 26
				illicit 23

Source: Data extracted from Illicit Drug Reporting System (IDRS) 2003, 2004, 2005, 2006; Jenkinson & O'Keefe 2006.

Morphine

Table 3.16 showed that some 44 per cent of the national IDRS sample used morphine in the six months prior to interview. Although illicit versus licit use is not reported for the national sample, rates of illicit use ranged from 30 per cent in the ACT to 70 per cent in the Northern Territory. Thirty-seven per cent of Victorian injecting drug users interviewed in the 2005 IDRS reported illicit use of morphine in the six months prior to interview (Stafford, Degenhardt, Black et al. 2006), and 39 per cent reported injection of morphine in the previous six months. The most common types of morphine used by Victorian IDRS respondents were MS Contin® (55%) and Kapanol® (27%) (Jenkinson & O'Keefe 2006). National and jurisdictional trends in morphine injecting are presented in Table 3.21.

Table 3.21: Proportion of IDRS samples reporting injection of morphine in the previous six months by jurisdiction, 2001–2005

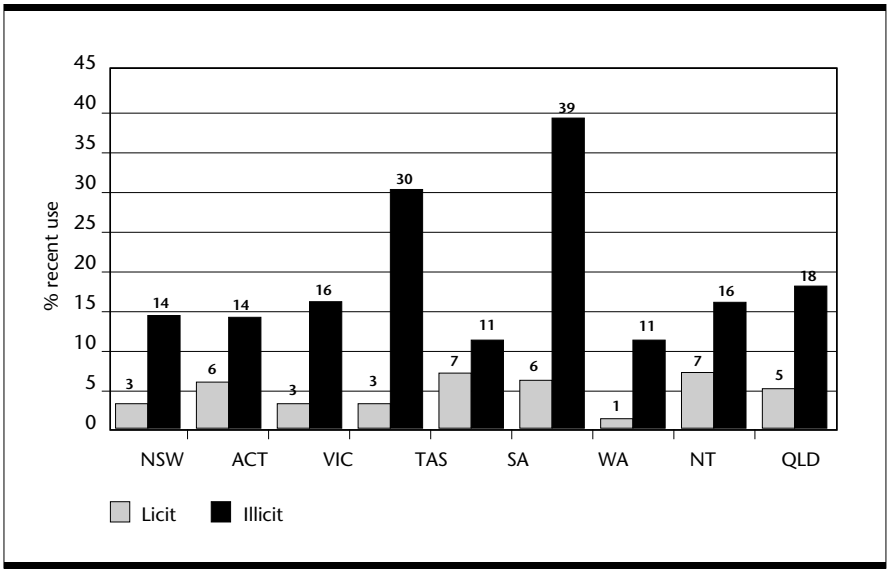
	National	NSW	ACT	VIC	TAS	SA	WA	NT	QLD
2001	40	12	33	31	72	34	32	84	31
2002	46	18	34	47	73	44	49	85	32
2003	40	20	49	39	69	42	40	80	40
2004	46	24	40	41	60	40	43	86	45
2005	41	24	30	39	55	34	48	79	28

Source: Stafford, Degenhardt, Black et al. 2006, p.115.

Oxycodone

For the first time IDRS interviewees in 2005 were specifically asked about the use of oxycodone. Nationally, five per cent reported licit oxycodone use and 18 per cent reported illicit use in the last six months. Nationally 87 per cent of those who reported recent (last six months) use of oxycodone reported illicit use. Figure 3.26 shows use of licit and illicit oxycodone in the previous six months by IDRS respondents in each Australian jurisdiction in 2005 (Stafford, Degenhardt, Black et al. 2006).

Figure 3.26: Licit and illicit oxycodone use in the previous six months by IDRS respondents in each Australian jurisdiction, 2005



Source: Stafford, Degenhardt, Black et al. 2006, p.116.

Among the Victorian sample, 17 per cent reported use of oxycodone in the last six months, with 15 per cent having injected the drug over this period. Eighty-two per cent of those Victorian injecting drug users who used the drug over that period said they mostly used illicit oxycodone over that period, with the most commonly used brand being OxyContin® (Jenkinson & O'Keefe 2006).

The Party Drugs Initiative

Data from the 2005 Party Drugs Initiative indicates that non-medical use of benzodiazepines and prescribed narcotic analgesics among regular 'ecstasy' (drugs sold as MDMA) users was less common than among regular users of injecting drugs. However, a comparison of Victorian data with that from the other states and territories, presented in Table 3.22, suggests that Victorian party drug users surveyed had higher rates of lifetime and recent (last six months) use of benzodiazepines and other opiates.

Table 3.22: Lifetime and last six months use of selected pharmaceutical drugs among recent users of 'ecstasy', Australian states and territories, 2005

	National N=180	NSW n=101	ACT n-126	VIC n=100	TAS n=100	SA n=100	WA n=100	NT n=82	QLD n=101
Benzodiazepines									
ever used (%)	42	51	23	54	40	46	49	28	45
used last 6 months (%)	27	39	12	37	25	26	39	17	24
Methdone									
ever used (%)	6	6	4	1	5	6	8	12	6
used last 6 months (%)	2	4	1	0	0	3	4	3	
Buprenophine									
ever used (%)	3	1	1	2	2	2	5	10	4
used last 6 months (%)	2	1	1	0	1	1	2	7	3
Othr Opiates									
ever used (%)	26	30	20	34	25	20	41	22	24
used last 6 months (%)	14	20	10	18	13	8	27	10	11

Source: Data extracted from Stafford, Degenhardt, Dunn et al. 2006, pp.11–12.

In 2005, only two participants (0.24%) in the Party Drugs Initiative national sample said benzodiazepines were their drug of choice and only 3 per cent (n=26) of the sample had ever injected, with less than 1 per cent (n=9) having injected in the preceding six months. Among those that had used benzodiazepines in the previous six months, the frequency of use varied from once (18%) to daily use (4%). The median number of days used was five, or nearly once a month (Stafford, Degenhardt, Dunn et al. 2006).

Regarding use of medications registered for the treatment of opiate dependence, nearly half (40%, n=6) of the national Party Drugs Initiative sample that used methadone reported daily use, suggesting they were in treatment. Of those 2 per cent that had used buprenorphine in the last six months, 73 per cent had swallowed the drug and 67 per cent had injected it. Over half (53%) reported using buprenorphine for 90 days or more in the preceding six months, also suggesting they were likely to be in buprenorphine treatment. Twenty-six per cent of the national sample had used 'other opiates' (including drugs such as morphine and pethidine) and 14 per cent had done so in the previous six months. Among those who used it in this period, the median days of use in the last six months was three days. Some 3 per cent had injected other opiates in the previous six months (Stafford, Degenhardt, Dunn et al. 2006). Recent users of ecstasy are another group where rates of prescription drug misuse are higher than the general population and will likely be an important sentinel group in monitoring misuse of these drugs.

Conclusion

There are necessarily limitations in the capacity of any research methodology to provide an accurate representation of the extent of any illicit drug use and misuse of pharmaceutical drugs in particular. While there are also limits on the

extent to which overseas trends are reflective of the Australian situation, there may also be good reasons to suspect that some of the major drivers of pharmaceutical drug misuse may be similar in countries such as Australia and the United States. Such factors include: increased use of these drugs in legitimate medical practice providing an opportunity for greater diversion to the illicit market; fluctuations in illicit drug supply; and the growth of largely unregulated supply of pharmaceuticals through the Internet. Given this, it is noteworthy that in surveys of the general population in both countries there has been relatively high rates of recent prescription drug misuse in general, and analgesic misuse in particular. Unsurprisingly, population rates of misuse in Victoria reflect the national figures.

Statistics on non-medical use of benzodiazepines and narcotic analgesics by injecting drug users in Victoria and nationally show variation in trends in drugs misused over time and between locations. Overall, recent trends in methadone and morphine have been relatively stable in Victoria and nationally over recent years. However, benzodiazepine misuse by injecting drug users has been stable or decreasing both in Victoria and nationally, with a clear reduction in temazepam injecting as a result of active steps to reduce the availability of the readily-injected liquid-filled gel caps. In addition, user education initiatives to combat its misuse and accompanying harms have been implemented. In contrast, as new drugs become available for treatment of opioid dependence or other conditions, there has been increases in their misuse by injecting drug users. For example, since the introduction of buprenophene to assist in the treatment of opioid dependance there have been increases in the misuse of this drug both nationally and in Victoria. Similarly, United States data suggests there has been a vast increase in the misuse of controlled release oxycodone tablets (OxyContin®) since its introduction. In Australia, slow release oxycodone tablets were introduced in 2001. Monitoring of oxycodone misuse by injecting drug users only commenced in the IDRS in 2005, but it will be interesting to see how trends in use of OxyContin® by this group unfold.

This chapter has discussed the extent of both benzodiazepine and narcotic analgesic use and abuse in Australia and Victoria. To a certain extent it has raised more questions than given answers. Some of these ongoing issues and questions for further discussion are listed below.

Questions for further consideration

Is data on the legal supply of pharmaceutical drugs in Australia important in understanding misuse of these drugs?

How useful are current data collections on pharmaceutical drug supply in Australia?

Is there a need for a publicly available analysis of supply of pharmaceutical drugs known to be misused in Australia?

How useful are current data collections for understanding the nature and extent of pharmaceutical drug misuse?

To what extent are these data collections used to inform policy and practice?

What additional statistics and other data should be collected pertaining to pharmaceutical drug misuse in Australia?

How can such data be better coordinated and most efficiently disseminated?

What research questions and projects are currently being developed with regard to the extent of pharmaceutical drug misuse?

What research questions and projects should be developed with regard to the extent of pharmaceutical drug misuse?

To what extent is international data on pharmaceutical drug misuse helpful in Australia?

What is the evidence of the impact of the 'heroin drought' on misuse of pharmaceutical drugs?

What has been the impact of restrictions of temazepam capsules on misuse of these drugs?

Is there a case for preventing the registration of other psychoactive drugs formulated in easily injectable liquid filled gel caps?

What are likely to be the emerging pharmaceutical drugs of misuse in Australia?

Is the data on prevalence of pharmaceutical drug misuse in Victoria timely and detailed enough to inform policy responses at the local level?

Is there a need for specific data collection or compilation to answer questions about pharmaceutical drug misuse among specific target groups such as culturally and linguistically diverse communities, Indigenous Australians, the elderly and rural Victorians?

4. The Adverse Consequences of Pharmaceutical Drug Abuse and Misuse

There are numerous problems that can occur when pharmaceutical drugs such as benzodiazepines and narcotic analgesics are used for non-medical purposes. This chapter provides an overview of these concerns. It should be noted that these drugs could also have adverse effects when used as prescribed and even under the care of a medical practitioner. A good example of this are the problems associated with long-term use of benzodiazepines. As TRANX (Tranquilliser Recovery and New Existence) Inc. explained in their submission to the Inquiry:

> In the case of the benzodiazepines, significant harm has been and continues to be caused to people taking these drugs in prescribed doses, but for inappropriately long periods of time. Many of these people have taken doses within the recommended daily dose limit, have only seen one GP and have taken the drugs as advised by their medical practitioner. It may be more appropriate to describe the drugs as being 'mis-prescribed' rather than 'misused'.[55]

As acknowledged elsewhere in this Interim Report, there is now widespread recognition that the use of benzodiazepines even at the appropriate prescribed dose for more than a few weeks can result in a dependence syndrome, and if the drug is abruptly ceased seizures can result.

> The main problem associated with long term use of the benzodiazepines is dependency. The withdrawal syndrome from benzodiazepines can be painful and protracted, making reduction from these drugs problematic. Withdrawal symptoms include headaches, depression, dizziness, loss of balance, nausea, and depersonalisation. The most common symptoms of withdrawal are extreme anxiety with panic attacks and insomnia – often the very reason for which the person was prescribed a benzodiazepine.[56]

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55 Submission of Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

56 Submission of Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

Moreover, the role of benzodiazepines in the risk of falls and fractures among the elderly is often cited as an adverse effect of these drugs. Although there are difficulties in attributing risk wholly or partly to a single factor, evidence has shown (Koski et al. 1996) benzodiazepine use, particularly use of multiple, high dose and long acting formulations (such as oxazepam and chlorodiazepoxide), is implicated in risk of injury among older patients (Tamblyn et al. 2005). Thus, the adverse effect of the medical use of drugs such as benzodiazepines is a very important community issue. However, as the focus of this Inquiry is the non-medical use of these drugs, this issue will not be addressed further in this chapter.

The misuse of benzodiazepines and prescribed opioids can also have an effect at a macro level, in terms of impacts on the health budget, such as through hospital admissions and ambulance call outs, crime rates and other outcomes at a population level. The impacts can be significant, as noted by Dr Rodger Brough who gave an excellent snapshot of both the immediate and 'ripple' effects of this from a regional Victorian perspective in his submission to the Inquiry:

> …there is a potentially dangerous and deteriorating situation for both healthcare workers (GPs, A&D workers and pharmacists) and many 'innocent' patients, related to a distinct shift to the preferential use of prescribed opioids over heroin by opiate users in South West Victoria. The virtual absence of heroin supplies in the region in the last 5 or 6 years, causally associated as I believe it is with the equally impressive rise in prescribed opiate users (and prescribed opiate 'abuse'), has created a heightened need for specialist pain management and pharmacotherapy services. Persistent advocacy has been determinedly ignored. At the same time, the cultural shift from the illicit market-place (of the heroin networks) to the dependence on the 'licit' opiate supply network (through the region's GPs and pharmacies) has a number of very worrying consequences that are becoming increasingly evident:
>
> - The use of this 'licit supply network' provides a great degree of 'cover' for the pernicious activities of the dedicated 'addicts' and makes effective policing and control much more difficult (for medicos and law enforcement alike).
> - The veneer of 'safety' and 'respectability' provided for this new breed of opiate addict by their 'association' with their 'de facto suppliers' (doctors and pharmacists) belies the real and malignant nature of the underlying problem.
> - Increased exposure to overt threats and 'intimidating requests' from opioid 'doctor shoppers' is effectively producing greater resistance from GPs and pharmacists in dealing with anyone who remotely looks like this 'new breed of opiate addict'.
> - Doctors (predominantly) and pharmacists (to the extent that some won't agree to dispense S8[57]) are effectively being perceived as the 'cause of the problem'.

57 That is Schedule 8 drugs. Schedule 8 drugs are subject to strict controls with regard to prescribing and dispensing. See Chapter 6 for further duscussion of drug scheduling.

- It is making it harder for people who are genuinely trying to seek help for chronic pain or drug problems to access the support and services they need and may tentatively seek. Furthermore, despite the DPU's apparent view to the contrary, it is no easy task to accurately pick these 'real sheep' from 'the wolves dressed up as sheep' – particularly so, when there is such limited specialist support available in the regional areas, and the 'wolves' are so deviously cunning.
- While both Federal and State health departments are aware of the issue, the particular wide-reaching detrimental consequences experienced in rural communities, beyond the population of drug users, are simply not appreciated.[58]

This chapter, however, primarily focuses on the effects on individuals and, to a lesser extent, significant others. The main reasons for this is that most of the adverse consequences of pharmaceutical drug *misuse* can be distinguished from the adverse effects of *medical use* of these drugs at the individual and community level. The exception to this is the impacts of benzodiazepines on aggression and violence – the so-called 'Rambo effect' – and the impacts of both the benzodiazepines and the opioids on psychomotor skills, which can contribute to motor vehicle and other accidents. Consequently, both these issues are addressed in this chapter.

Another important issue not addressed in this chapter is the use of short acting benzodiazepines such as flunitrazepam (eg. Rohypnol®) as a 'date rape' drug. This problem has been well summarised by others (Taylor, Prichard & Charlton 2004; Drugs and Crime Prevention Committee 2004, 2006), and its use in that context to administer to another person to sexually assault or otherwise take advantage of them sets it apart from the adverse effects of self-administered misuse of benzodiazepines and pharmaceutical opioids.

The chapter begins with a short account of the extent of emotional and social consequences that can occur as a result of non-medical use of prescription drugs. This is followed by summaries of the *drug specific* adverse effects of benzodiazepines, followed by opioids. These include sedation, memory problems, impairments in driving skills, dependence, withdrawal and overdose.

The next section focuses on the medical problems associated with the injection of diverted pharmaceutical drugs. An account of the development, consequences and responses to the injecting of temazepam gel capsules is presented, as this has been one of the most worrisome examples of adverse consequences of the misuse of pharmaceutical drugs. Yet conversely this has also been an issue where there has been a successful, multi faceted response across the drug-user community, government, and the pharmaceutical industry. Problems associated with the injection of ground-up tablets as a result of

58 Submission of Dr Rodger Brough, Western Region Alcohol and Drug Centre (WRAD) in Warrnambool, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

injecting the talc incorporated in them are then described (talc gramulatosis). This is followed by an account of problems that can occur as a result of injecting oral doses of medications that have been contaminated with saliva. In such cases people undergoing drug substitution treatment such as methadone, or buprenorphine treatment, sometimes retain their dose in their mouth so it can be spat out and then injected.

The chapter concludes with a short section looking at Victorian service utilisation statistics as indicators of the extent to which these harms are realised in the Victorian community. This includes, where available, ambulance attendances, inpatient hospitalisations and specialist treatment service presentations for benzodiazepines and prescription opioids.

Social and emotional consequences of non-medical use of prescription drugs

As noted by CASA (2005), non-medical use of prescription drugs can cause problems in relationships with family and friends, employment and educational problems, and legal problems. Indeed, non-medical users who are dependent on pharmaceutical drugs can experience social, emotional and health problems at rates comparable to users of so-called 'hard drugs'. CASA's analysis of data from the 2003 United States National Survey on Drug Use and Health (NSDUH) found that abusers of controlled prescription drugs experienced these problems at similar or higher rates than alcohol abusers, but at lower rates than those problems occurring as a result of illicit drug use. However, those misusing prescription drugs at a level that met the diagnostic criteria for 'abuse or addiction' suffered these problems at rates similar to dependent heroin users. See Table 4.1.

Table 4.1: Impact of illicit drug use and pharmaceutical drug misuse on users, United States, 2003 (per cent of respondents)

	Abusing						Using		
Problems	All Controlled Prescription Drugs	Opioids	Tranquilizers	Sedatives	Stimulants	Alcohol	Cocaine	Heroin	Clinical Abuse or Addiction All Controlled Prescription Drugs
Emotional or mental health problems	7.4	6.6	4.5	9.5	10.7	8.5	18.5	46.2	46.1
Family/friendship problems	5.1	4.6	3.9	7.6	7.6	7.6	14.6	33.0	37.1
Serious problems at home, work or school	4.6	3.9	3.8	6.7	7.6	4.2	12.6	36.8	37.4
Trouble with law	1.8	1.5	1.5	3.4	4.1	2.1	5.6	13.2	14.9
Worsened health problems	2.5	2.0	1.7	3.9	1.8	2.9	3.4	2.6	11.7
Used drug while doing dangerous activities	5.4	4.7	4.7	7.8	7.5	13.0	13.9	22.8	43.5

Source: National Center on Addiction and Substance Abuse (CASA) 2005, p.43.

A personal account given to the Inquiry described a mother's ongoing relationship difficulties and her struggle to avoid prescription drug misuse to cope with these pressures.

> I have a 16-year-old daughter who is currently finding it very difficult to come to terms with a mother that has had an addiction. She left me a note near the kettle the night before last – it was rather sad really – saying that she has had to lie to people to cover up things that I have done in the past. I have tried very hard to make amends with Jane. I am finding a lot of difficulty talking to her at the moment – (a) that she is 16; (b) I cannot justify the lies in the past. All I have done is to try to be up-front with her, and talk about the addiction and the dependency. But at the moment she is a very angry 16-year-old. I currently have a broken sliding door at the back. She is a very angry young girl.
>
> I would like her to get help somewhere but at the moment it is all me. She sees herself as a reflection of me. I find the whole thing at the moment is very confronting. That is why I am having a lot of difficulty staying away from, or trying to keep away from, medication. It is so tempting to go back and block out that whole emotional thing that I can feel now occurring.[59]

There is often a strong relationship between severe dependence on benzodiazepines and pharmaceutical opioids and other substance use and mental health problems. For example, a Canadian study of 30 people undergoing inpatient treatment for benzodiazepine dependence found all had used benzodiazepines and other drugs at high doses for long periods. Most had substantially impaired social functioning and lifetime psychiatric diagnoses, notably depression (33%), other drug dependence (100%) and panic disorder (30%). Most (83%) had another current substance use problem including opioids (67%), cocaine (13%) or multiple substances (17%). Other current diagnoses included generalised anxiety disorder (20%) and panic disorder (13%) with substantial proportions having personality disorders (antisocial, 42%, avoidant 25%, and borderline 17%) (Busto, Romach & Sellers 1996).

Research suggests that these types of harms are particularly experienced by women, especially when the drug abuse is restricted to benzodiazepines alone. A submission from Darebin City Council that draws upon Boyd's 2003 research suggests:

> Women are at greater risk of harms from the unsafe use of medications. Medication use was prevalent amongst women who had experienced childhood sexual abuse and who had a history of family violence, both as a child and in current or recent relationships.
>
> Data collated for DAREBIN*safe*'s *Injury Profiles 2004* show a disturbing trend in the use of medications to assist suicide and self-harm attempts:

59 'Mary', 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 Hearing, Melbourne, 20 June 2006. The name of the person and others mentioned who gave evidence has been changed to protect their anonymity.

> There are over 300 presentations to hospital emergency departments each year for self-harm and suicide. Around 70% of attempts use medications. In Darebin, women are more likely to attempt suicide and are more likely to use medications in their attempts.[60]

Darebin City Council also suggests that:

> While there is no doubt that benzodiazepines are used as part of polydrug use, this submission urges caution in assuming that this is where the bulk of harms occur…Research conducted in Darebin and Moreland in 2002/03 found that contrary to local assumptions, the harmful impacts of benzodiazepines were felt by women who were not taking any other illicit substances. The research…instead found that – in particular – the women who were admitted to hospital or attended by ambulance were not using other substances at the time of their overdose.[61]

The fact that there may be a significant minority of people, particularly women, who misuse benzodiazepines without recourse to other drugs also has implications for the development of appropriate treatment services**.** This will be discussed later in Chapter 9 of this Interim Report.

Drug-specific adverse effects from misuse

Benzodiazepines

In terms of the contribution of benzodiazepine use to mortality in general, it is worth noting the evidence to the Committee given by Professor Olaf Drummer of the Victorian Institute of Forensic Medicine. He explained:

> Over the years benzodiazepine has been, perhaps second to alcohol, the major drug of interest or concern to us at the Institute and, indeed, to the coroner as well. They are of concern because they are present in a large number of cases of various types. In terms of drug deaths, they are present in about half to two-thirds, depending on the type of drug death, not because they themselves are so dangerous that by themselves they cause people to die but they are often misused with other drugs and they add to the effects of other drugs, whether they be prescription drugs such as antidepressants, or people who choose to use heroin...
>
> There are a variety of situations where benzodiazepines play a role – and occasionally they cause death by themselves. In motor vehicle accidents it is certainly by far the most commonly seen prescription drug. … As a prescription or legal drug they are by far the most common type. It has been well shown

60 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

61 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

> that their misuse leads to people who are impaired and unable to drive properly, and there is an increased risk of them having a crash.[62]

While recognising that there is anecdotal and other evidence that suggests a sizeable cohort of people who abuse benzodiazepines do so without contemporaneously abusing other drugs, it nonetheless remains the case that most misusers of benzodiazepines are 'polydrug users' in that they use a number of drugs in combination or at different times (Rall 1992; Ashworth, Gerada & Dallmeyer 2002).[63] Perhaps the most notable feature of benzodiazepine misuse by polydrug users is that the doses taken vary enormously (Ashworth, Gerada & Dallmeyer 2002) but can be many times greater that the usual therapeutic dose. For example, Ashworth and colleagues cite earlier work suggesting that a typical dose for an injecting drug user could be between 40mg and 100mg of temazepam or diazepam per day, but that use of over 1,000mg per day is not uncommon and some addicts consume over 3,500mg per day.

With regard to the adverse effects of benzodiazepines, Dr Malcolm Dobbin observed in his evidence to the Committee:

> Benzodiazepines cause sedation. They can contribute to central nervous system depression separate from other opiate central nervous system depression, and that, working through a different pathway, can contribute to coma and death. It also causes people to be confused, if they have taken a number of drugs and, particularly if they have co-abused it with alcohol or other CNS depressants as well, [they] can cause impaired driving. It contributes to culpable driving as well. It can cause what is called anterograde amnesia: people can remember taking the tablets but they do not remember what happened afterwards. People can go into a kind of a fugue state and shoplift in front of a shop assistant and then, when they find themselves in the cells, not remember what they did. That has implications for people who might seek treatment and may have some understanding of what they have done while they have been counselled and undertake to do certain things, but then forget their appointments or that they have made appointments. Their compliance with treatment might be impaired as well.
>
> Of course, benzodiazepines can cause dependence. People can experience an uncomfortable and quite dangerous withdrawal syndrome. It is quite

62 Professor Olaf Drummer, Head (Forensic and Scientific Services), Victorian Institute of Forensic Medicine, 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 Hearing, Melbourne, 13 July 2006.

63 Polydrug use is defined by UNODCCP (2000) as 'the use of more than one psychoactive drug either simultaneously or at different times. The term is often used to distinguish persons with a more varied pattern of drug use from those who use one kind of drug exclusively' (p.56).

> dangerous because it can cause seizures. Once people become dependent on them, if they stop suddenly they can have a seizure, similar to an epileptic fit.[64]

Sedation

The sedation associated with benzodiazepine misuse, particularly at high doses, can contribute to concentration and memory problems to a greater extent than other drugs of abuse[65] (Ashworth, Gerada & Dallmeyer 2002). Memory problems can also lead to chaotic behaviour and disorganisation. For instance, risky drug use can take place when users forget whether the needle they are about to use has been used previously by someone else. Similarly, sex workers who use temazepam before seeing their clients can be at risk as they are reported to be less able to practise safe sex when affected by such drugs (Ashworth, Gerada & Dallmeyer 2002).

Amnesia

Amnesia is listed as a possible adverse effect for all benzodiazepines. This type of amnesia is anterograde; that is, the memory of events occuring after taking benzodiazepines is affected, while long-term memory remains intact (Barker et al. 2003). The cause of benzodiazepine-induced amnesia is unclear. It has been linked with the sedative effects of the drugs and also with the neurological systems responsible for the laying down of new memories (Ashton 2002). Whether these effects on memory are permanent or resolve once the drugs are removed is also unclear. Some studies have found that short-term, or recent, memory problems are still present up to two years after the drug has been discontinued, while others have found little effect following long-term use (Barker et al. 2003). The severity of the amnesic effect is affected by the type of benzodiazepine used, the dose taken and the method by which the dose is administered (ie. oral versus injection) (Barker et al. 2003).

Contribution to overdose

There have been few reported cases of overdose death following the ingestion of any of the benzodiazepine drugs on their own (Gossop et al. 2002). Indeed, benzodiazepines were introduced as a safer alternative to the barbiturates which they have all but replaced. Most overdose deaths involving benzodiazepines also involve the consumption of other drugs, as Dr McDonough, Medical Director of Drug and Alcohol Services at Melbourne's Western Hospital explained in his evidence to the Inquiry:

> Since the fifties there has been a dramatic decline in "tranquillizer" overdose mortality, and since the increased availability of benzodiazepines there has been a dramatic decline in overdose death. Most overdose cases that present to our

64 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, 29 May 2006.

65 For example, a loss of concentration due to the sedative effects of these drugs can cause driver impairment and consequent road trauma, see discussion later in this chapter and in Chapter 6.

> hospitals now are able to be discharged within 24 hours. They do not generally have a fatal outcome. There surely are some (still "too many") but the overwhelming majority are non-lethal and the overwhelming majority, as I said earlier, present as cases that we in the hospitals call 'cocktails', because there is often alcohol with some benzodiazepines – sleeping pills washed down with some grog. Most of those people survive quite well, and those that do not do well often have some other misadventure associated with that cocktail. For example, they fall back and vomit and the vomit gets inhaled, and that can have a lethal outcome or, at the very least, can give them serious pneumonia.[66]

Although rare, benzodiazepine-only overdose deaths have been recorded. For example in Australia, Drummer and Ranson (1996) reported on 16 deaths resulting from toxic amounts of benzodiazepines between 1990 and 1994. Deaths that involved a combination of benzodiazepines and other drugs were excluded leaving five of the 16 deaths attributed to benzodiazepines alone. In order of prevalence, the benzodiazepines involved were nitrazepam, temazepam, oxazepam and flunitrazepam. The authors suggested that flunitrazepam might be more toxic compared to other benzodiazepines (Drummer & Ranson 1996).

Thus, while the effects of benzodiazepines are usually benign when taken alone, even in overdose, they can potentiate the effects of other central nervous system depressants such as alcohol and opiates, sometimes with lethal effects.

Psychomotor impairment

Given the common side effects associated with the benzodiazepines – sedation, drowsiness, ataxia, psychomotor slowing, motor in-coordination 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. 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, including benzodiazepines, using modern analytical techniques and clearly provide a report to that effect to the police and to the courts.
>
> In those sorts of cases of driving whilst impaired, which is the offence, about two-thirds of drivers are using benzodiazepines. Many of those, as I am told by the police, either have no legal prescription for the drug or are somehow

66 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 20 June 2006.

> misusing their legal prescription for the drug. That is a factor in two-thirds of drivers picked up as impaired.[67]

In his written submission Professor Drummer summarised cases that had been referred to the Victorian Institute of Forensic Medicine. This showed that benzodiazepines were present in 65 per cent of impaired drivers (defined above by Professor Drummer), 15.8 per cent of injured drivers and between 3 and 5 per cent of fatally injured drivers. Professor Drummer also noted that 33 per cent of injured women drivers aged more than 56 years tested positive, double the overall figure.[68]

When asked by the Chair, Professor Drummer explained how driving performance could be impaired by benzodiazepines.

> They [benzodiazepines] tend to have manifestations that are similar to alcohol misuse. Their reflexes are not as good; perhaps they are wobbling on the road a bit; they are drifting in and out of lanes; their attention span is reduced; their peripheral vision is reduced…A police officer could well think they are drunk but be surprised there is no alcohol present in their breath.
>
> Clearly there are extremes. There is the driver whose vigilance is affected: they are sleepy as a result of the medication; they are drifting off; they run off a road and perhaps run into an object or into another car or into a fixed object along the roadside. There, it is a bit harder sometimes to individually say, 'This is a cause of the accident', even though the drug is found in their body. At the point where they are clearly driving erratically and are picked up by the police before they do something silly they are assessed to be not sober but in fact it is caused by drug use rather than by alcohol use.[69]

Dr Drummer's evidence concurs with that in the published literature. On-road driving studies have found that the benzodiazepines significantly impair driving competence. For example, Alford and Vester (2005) reviewing six such studies found that the impairment associated with some benzodiazepines was the equivalent of driving above 0.10 per cent blood alcohol level. In a comprehensive review of the literature published between 1970 and 2002 on benzodiazepine use and driving, Kelly, Darke and Ross (2004) found that, after cannabis, the benzodiazepines were the most commonly detected drug in drivers who had been involved in road crashes.

In correspondence to the Inquiry in response to questions about the feasibility of extending the random roadside screening of drivers for cannabis and

67 Professor Olaf Drummer, Head (Forensic and Scientific Services), Victorian Institute of Forensic Medicine, 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 Hearing, Melbourne, 13 July 2006.

68 Submission of Professor Olaf Drummer, Head (Forensic and Scientific Services), Victorian Institute of Forensic Medicine, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

69 Professor Olaf Drummer, Head (Forensic and Scientific Services), Victorian Institute of Forensic Medicine, 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 Hearing, Melbourne, 13 July 2006.

amphetamines to other drugs, Dr Martin Boorman explained that:

- There is limited research information available in respect of what level of benzodiazepine type drug present in a person produces impairment of psychomotor skills to such an extent as to result in an inability to drive a motor vehicle safely.
- There is limited research information available to indicate what level of benzodiazepine type drug present in a person may be considered a therapeutic level as opposed to a level consistent with misuse and the presence of impairment.
- The currently available technology to test saliva for benzodiazepine type drugs in a roadside situation is relatively limited in terms of accuracy in respect of the level of drug present in a sample.

It is believed there is a need for further research and investigation of the issues associated with the use of benzodiazepine type drugs and the driving of motor vehicles before a decision is made in respect of whether an extension of the random drug testing regime to include benzodiazepine type drugs should be adopted.[70]

Dependence and withdrawal

The Interhospital Liaison Group provided the Inquiry with a concise but informative summary of the issues regarding benzodiazepine dependence and withdrawal:

Benzodiazepines lead to rapid, profound neuro-adaptation[71] which leads to:

- tolerance – marked by diminished effects at equivalent dose and reduced sensitivity to high doses
- dependence – unpleasant, dangerous manifestations of neuro-adaptation when dosage is reduced/ceased.

The benzodiazepine dependence syndrome is very difficult to treat, often leading to months of unpleasant physiological and psychological manifestations that require significant resolve to endure. Of particular difficulty are the symptoms of:

- anxiety
- insomnia
- agitation

which may be accompanied by physical signs of tachycardia and hypertension, and may be markers of an increased risk of seizure phenomena.

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70 Correspondence from Dr Martin C Boorman, Inspector, Traffic Alcohol Section, Technical Unit, Victoria Police, to the Drugs and Crime Prevention Committee, 27 July 2006.
For further discussion of the legal consequences of drug impaired driving due to the ingestion of prescription and/or other drugs, see Chapter 6 of this Interim Report.

71 Neuroadaption is a term used to describe what happens at a cellular level in the brain during physical dependence as the cells change to accommodate the presence of a drug in a new 'normal state'. It is defined by the UNDCP as 'Adaptation by the central nervous system to repeated administration of psychoactive drugs resulting in increased tolerance and sometimes a withdrawal syndrome following cessation of drug use' (UNDCP 2000, p.48).

> This withdrawal syndrome is not dissimilar to alcohol withdrawal apart from having a time course of weeks to months rather than days. There is also the issue of cross-tolerance to consider; benzodiazepine and alcohol dependence often coexist and patients may switch between these as a strategy to cope with withdrawal.
>
> One of the difficulties of engaging dependent individuals in treatment is their extreme fear of the anxiety that accompanies withdrawal and the positive reinforcement of the relief of symptoms with benzodiazepines.[72]

In evidence to the Inquiry Dr Frank Giorlando, Interhospital Liaison Group, described the extent of discomfort of benzodiazepine withdrawal:

> ...I think that benzodiazepines are as much a problem as heroin, alcohol, the so-called hard drugs. They cause a great degree of suffering to people because they become dependent, and all the things that originally these drugs were prescribed for become worse over a long period of time. The sleeping quality becomes worse, the anxiety is terrible without medication or if there is a reduction in medication, and one of the worst things about benzodiazepines is that the withdrawal symptoms last for months upon months, whereas with alcohol, for instance, most of the physical withdrawal symptoms are over in a week. I think they cause a massive amount of suffering in the community.[73]

There is a small body of literature relating to the use of and dependence on benzodiazepines among illicit drug users, much of it conducted in the United Kingdom and Australia. In one study in London, 36 per cent of 169 admissions to a drug treatment centre met the criteria for benzodiazepine and other pharmaceutical dependence and 43 per cent of these underwent a withdrawal programme for these drugs (Williams, Oyefeso & Ghodse 1996). Another English study reported that 28 per cent of 158 injecting drug users were classified as having ever been dependent on benzodiazepines, although this study did not report on rates of current benzodiazepine use (Dinwiddie et al. 1996). In Sydney, Ross, Darke & Hall (1996, 1997) found that approximately one-quarter of heroin users who also used benzodiazepines displayed some degree of dependence. In a later Sydney study using a different method of classifying dependence, Ross and Darke (2000) found 22 per cent of current benzodiazepine users were found to be 'dependent' on the drug with 3 per cent being 'mildly dependent', 7 per cent 'moderately dependent', and 12 per cent 'severely dependent'. Ross and Darke (2000) concluded that:

> A disturbingly high proportion of heroin users meet the criteria for benzodiazepine dependence, a condition that should be regarded as a significant marker for co-morbidity among this group (Ross & Darke 2000, p.1785).

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72 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.

73 Dr Frank Giorlando, Addiction Medicine Registrar, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

Paradoxical aggression – the 'Rambo effect'

Benzodiazepines are frequently prescribed for their tranquillising effect in the relief of insomnia and anxiety. Paradoxically, they can trigger incidents of central nervous system stimulation, which manifests as talkativeness, mania, anxiety, restlessness and sleep disturbances and nightmares (Barker et al. 2003). This can also result in episodes of acute rage and extreme aggression which is sometimes referred to as the 'Rambo' effect, described as: 'a paradoxical increase in aggressive or disinhibited behaviour is experienced by some, both at therapeutic doses and at the much higher levels consumed by illicit users' (Ashworth, Gerada & Dallmeyer 2002, p.391).

Dr Malcolm Dobbin, Senior Medical Adviser at the Drugs Policy and Services Branch of the Department of Health in Victoria described the effect to the Committee in his evidence to the Inquiry:

> …the Rambo effect. That is identified in the forensics scene. As it has been described to me, people feel invisible and invincible where…they are quite unaware of what they are doing and are detected committing minor crime. They can also get into this Rambo thing, where they can become violent and feel invincible. A Belgian doctor has identified the Rambo effect and written about it, but I have heard it described locally as well.[74]

Dr McDonough also described the 'Rambo effect' to the Committee:

> The Rambo effect on the street has been reported to be associated with some forms of crime that were committed when people built up the 'Dutch courage'. I have spoken to patients who relate this story very well, saying that, "…We had to do a 'burg' on the local 7-Eleven: I was a bit nervous: I hadn't done that kind of thing before so I heard you take a handful of 'Rohies' [Rohypnol®], half a dozen or more, and they give you a sense of confidence and elation and so you can do it." That is the 'Rambo' effect. They feel like they have superstrength.[75]

While the mechanisms by which such aggression is triggered are unclear, it has been hypothesised that while benzodiazepines reduce anxiety through depression of the central nervous system they may also reduce inhibitions and result in impaired judgement (Ben-Porath & Taylor 2002). A number of laboratory-based studies have tested this hypothesis by administering diazepam or a placebo to male and female volunteers and challenging them within a controlled competition. The results showed that those who had taken the diazepam were more aggressive than those who took the placebo (Taylor & Chermack 1993). Other laboratory-based experiments have shown similar effects with lorazepam and oxazepam (Ben-Porath & Taylor 2002). These

74 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, 29 May 2006.

75 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 20 June 2006.

experiments were performed under controlled conditions during which other drugs or alcohol were not involved and therapeutic doses of benzodiazepines were administered. Under conditions that are uncontrolled, where other drugs are likely to be involved and benzodiazepines consumed in excess of therapeutic doses, the situation can result in serious crime and significant harms.

In a study of male forensic psychiatric patients in Sweden, 30 per cent of the 60 subjects were found to be abusers of flunitrazepam and indicated a preference for this benzodiazepine because it gave them feelings of 'power and self-esteem', 'reduced fear and insecurity' and 'stimulated the belief that nothing is impossible' (Daderman & Edman 2001). When comparing the group of flunitrazepam abusers with non-abusers, the authors found that, although there were no differences between the groups in terms of the actual violent crimes, those in the flunitrazepam group were significantly more likely than non-users to have been previously admitted as forensic psychiatric patients for weapons offences, drug-related offences and theft (Daderman & Edman 2001).

In Germany, an estimated two-thirds of heroin users are reportedly dependent on flunitrazepam. When intoxicated with flunitrazepam the behaviour of these people caused considerable concern due to the 'aggressive, criminal and self-destructive behaviour' that apparently was affected by the amnesic effects of flunitrazepam (de Crespigny & Wodak 1995). Further evidence that flunitrazepam is associated with aggression and violence was found in the report of an Australian study investigating factors affecting young drug users' completion or cancellation of parole. The following quotes illustrate the problem:

> We've had kids coming in here when they've been 'Rohied', and not knowing the next day they've been in time loss, they lose days at a time. With 'Rohies' [they] steal cars, go joy-riding and then not know what they've done – riding dangerously or in a manner which could cause injury and having no recollection of doing it. They get charged, but don't know where they got the car from or how it happened – Avil,[76] car-sickness tablets have the same effect (Alder & Read 1992, p.26).

76 There have been other concerns expressed with regard to the motion sickness tablets Avil®. For example, a submission from Carol Andrew, a psychiatric nurse with Moreland Continuing Care Mental Health Programme states:

'In my experience this medication [Avil] plays a major role in presentations of psychosis and aggression, but there is very little documented about its abuse.

What I know is only anecdotal unfortunately, but it is a common practice amongst "those in the know" particularly psychiatric patients, to take a packet of Avil, in one sitting, often with alcohol to wash the tablets down, and then be in a "cloud 9" haze for a period of time, until they come down. Then during this period people can present as very psychotic as if they are in Delerium Tremens; seeing spiders crawling over them and their surrounds, or being irrationally violent.

The chemist our clinic deals with no longer stocks Avil for this reason, but I also understand that it is generally available over the counter through other chemists. I would be very interested to see this drug reassessed for its over the counter availability'. (Submission of Ms Carol Andrew to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006).

Further discussion of Avil® is beyond the scope of this Interim Report. It may need to be considered further, however, should this Inquiry be continued at a later stage.

and,

> there was a large commotion outside work at the project one night…and here were all the kids we were dealing with … they had an iron bar and they had assaulted the tram driver on the basis he was Asian. They put his head through the window and then kept pumping his head on the broken jagged edges of the glass…they claimed innocence on the basis they had no intention because they were so pilled (Alder & Read 1992, p.26).

Opioids

Most of the adverse effects of the pharmaceutical opioids such as methadone, morphine, and oxycodone are similar due to their central nervous system depressant effects, and are therefore dealt with together in this section. There are other adverse effects specific to some of these drugs that are addressed separately. Opioids lower respiration rates and heart rates and suppress reflex reactions such as coughing. They dilate blood vessels producing a feeling of warmth. They may also cause slow bowel activity producing constipation. Other adverse effects of opioid use include: sweating; muscles and joint pain; reduced libido; skin rashes and itching; sedation; fluid retention; loss of appetite; nausea and vomiting; abdominal cramps; dry mouth resulting in tooth decay; and irregular menstruation (Downie & Kettle 2000).

Saunders and Young note that:

> Opioids such as heroin have little toxic potential per se. They may, however, cause anoxia [lack of oxygen] due to overdose because of the variable quality of street drugs and co-use with other drugs acting as central nervous system depressants. Neuropsychological damage can result from anoxic episodes and subsequent necrosis [death] of brain tissue. Ancillary problems can occur from, for example, cigarette burns due to smoking while in a drowsy drug-induced state, anorexia [poor appetite] or nausea leading to poor nutrition, or reproductive system impairment, for example menstrual irregularities. The greater part of the associated morbidity is related to injecting drug use (Saunders & Young 2002, p.39).

Sedation

One of the classic adverse effects associated with heroin use which is also apparent with other central nervous system depressant use, particularly soon after injecting, is what is called being 'on the nod' or 'gouching'. This acute intoxication results in drifting in or out of consciousness, but without the signs and symptoms of a opioid overdose such as difficulty breathing, turning blue, lost consciousness, collapsing or being unable to be roused (Strang et al. 1999).

Psychomotor impairment

Given the comments above regarding the amounts of diverted pharmaceuticals which might be consumed by some non-medical users one could assume that at high doses, and particularly among people with a low tolerance to opioids,

driving ability will be adversely affected. However, work by Drummer (1994) suggested the risk of an accident for drivers affected by opioids may be small. Analysis of crash and toxicological data from 1,045 fatally injured drivers in Victoria, New South Wales and Western Australia found opioids were detected in only 2.7 per cent of the sample while alcohol was detected in 36 per cent. Of the 28 opioid positive group, 17 tested positive for codeine and nine for morphine, while only seven were positive for methadone. In only 1.1 per cent (12 cases) of the total sample, opioids were the only drugs detected in the dead drivers' blood. Drummer and colleagues then used a method called 'Responsibility analysis', to assign a relative crash risk for opioids on the basis of driver responsibility. This suggested that that the relative risk of the drivers detected with opioids only, and opioids plus alcohol, was not significantly higher than for the drug-free drivers. However, Drummer suggested caution in interpreting the results given the small numbers involved.

More recently Lenne et al. (2000) reviewed the literature on performance studies including laboratory studies, driving simulator studies and on-road driving studies and concluded that opioids, and methadone in particular have only a modest impact on driving skills. Nevertheless, they noted that other countries' states apply driving restrictions to methadone clients.

Tolerance and withdrawal

Tolerance to opioids involves a shortened duration and reduced intensity of their analgesic, euphoric and sedative effects. This means once dependent, people need larger or more frequent doses to have the same effect. There are large individual differences in the development of tolerance, and tolerance to the different effects of these drugs does not develop at the same rate. Thus even chronic, long-term users can experience the respiratory depression effects associated with opioid use, but might experience less of the pleasant euphoric effects. Most people experience some withdrawal symptoms even in mild reduction of dosage (Young et al. 2002).

> Signs of opioid withdrawal can start to occur within four to six hours after the last dose, depending on the half-life of the opioid that has been abused. Maximum effects occur normally after 36 to 72 hours, but this will vary according to opioid; if untreated, effects will take five to 10 days to subside. The severity of the withdrawal symptoms increases with the size of the opioid dose and duration of dependence. The symptoms of opiate withdrawal start initially with anxiety, craving, restlessness, lacrimation [teary], yawning, sweating and rhinorrhoea [runny nose]. A reliable early sign of withdrawal is a respiratory rate greater than 16 breaths per minute. Other symptoms include mydriasis [prolonged dilation of the pupil], piloerection [goose bumps], tremors, muscle twitch, hot and cold flushes, aching muscles and anorexia. In severe cases, tachycardia, hypertension or hypotension may occur (Downie & Kettle 2000, p.244).

There is not a great deal of literature with regard to dependence on pharmaceutical opioids among illicit drugs users. This is probably because there

is a recognised dependency syndrome related to all opioids, which has been described above. It is reasonable to believe that people using these drugs illicitly are at high risk of becoming dependent and that the dependence will be similar to that for other drugs in this class. Furthermore, much opioid use among injecting drug users in Australia and elsewhere is typically polydrug use. It is common for this to entail the use of heroin, in combination with benzodiazepines, pharmaceutical opioids, and/or a range of other drugs including alcohol. Given this, it is unsurprising that there is paucity of literature on dependence due to non-medical use of pharmaceutical opioids.

One exception to this is a small number of studies undertaken in the United States on OxyContin® dependence. This is probably because of the rapid growth in the spread of this drug in that country and its use beginning in mid-adolescence for some with relatively little or no other prior opioid use or heroin use (Katz & Hays 2004).

Two cases from the study by Katz and Hays (2004) are presented here. They show how adolescents may quickly develop serious addictions to OxyContin®:

> This 18-year-old single white girl with no known history of prior drug abuse reported using OxyContin for 2 years, on a daily basis for the previous year and a half. She snorted the OxyContin and had recently been leaving her infant son with her mother so she could spend her time using drugs. She reported selling all of her belongings and described not taking insulin for her diabetes because of her drug use, which escalated to 150 and then 200 mg of OxyContin per day. As a result of this, she dropped out of school and was spending most of her time crying, unable to sleep and unable to eat. She was finally admitted to an acute inpatient unit for detoxification from OxyContin.
>
> This 17-year-old single boy described using OxyContin for 1 month. His substance use had begun with cigarettes at age 11 and escalated to marijuana at age 12 and cocaine at age 16. He stole the OxyContin from his mother's supply and quickly escalated his use to 100 mg a day, which he snorted. The OxyContin use rapidly supplanted the use of all other substances and resulted in inpatient admission for detoxification 1 month after his use began (Katz & Hays 2004, p.232).

Another study using a small sample (n=10) described how new initiates to heroin use had commenced that drug after first becoming dependent on prescription opioids such as OxyContin®. Those interviewed reported turning to heroin after developing tolerance to OxyContin® and then experiencing withdrawal when they could no longer access the drug (Siegal et al. 2003). While acknowledging that these findings were limited to a very small sample size, the authors postulated that non-medical use of opioids such as OxyContin® could provide a new pathway to heroin use.[77]

77 Oxycontin is discussed further in the context of the acquisition of prescription drugs in Chapter 5 of this Interim Report.

Opioids and overdose

Most users of heroin also use benzodiazepines and prescription opioids. Heroin users are about 13 times more likely to die in any one year than their age-mates who do not use heroin (English et al. 1995), with annual mortality rates of between 1–3 per cent (Darke & Zador 1996). Although there has been an unprecedented decline in heroin-related overdose in Victoria (Woods et al. 2006), as elsewhere in this country, since the 'heroin drought' commenced in early 2001, overdose remains a real risk for many users of heroin and other opioids.

> Still to this day there will be a number of cases – of the order of 20 to 30 cases [of opioid overdose] in Victoria each year – where people die from methadone. Some of that is methadone they have got from, we think, an associate, particularly illicit methadone, or the doctor has unwittingly overestimated their requirement for methadone based on their heroin usage, and that has created a problem for them. That is a lot less than what we had in the early 1990s when DHS, as a result of some inquests, changed the way it allowed methadone to be dispensed by doctors, and there was a restriction on the maximum dosage they could prescribe under certain situations, but there still is a difficulty in doing that by some prescribers. A bit of doctor-shopping goes on in terms of takings drugs home and giving them to their friends. In New South Wales it is a bigger problem because of the way they do it [dispense takeaway methadone], so in that sense we have less of a problem here but there could still be more done. There is the difficult issue about the availability of drugs – people need the drug versus more regulations, more paperwork – to somehow control the relatively few number of people who choose to do the wrong thing.[78]

Heroin-related overdose deaths are usually polydrug deaths

Most heroin-related overdose deaths are associated with polydrug use; that is, a number of drugs and/or alcohol used in combination. Turning Point Alcohol and Drug Centre remarked in a submission to this Inquiry that:

> Benzodiazepines were detected in 71 per cent and morphine in 16 per cent of heroin related deaths in 2001 (Wallington et al 2002). In addition, a recent examination of risk behaviours associated with non-fatal heroin overdoses attended by the Melbourne Metropolitan Ambulance service (July 1999 to May 2001) found a higher likelihood of benzodiazepines or alcohol use in the 12 hours prior to overdose event (Dietze, et al., 2005).[79]

78 Professor Olaf Drummer, Head (Forensic and Scientific Services), Victorian Institute of Forensic Medicine, 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 Hearing, Melbourne, 13 July 2006.

79 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

Despite such data, it should be noted that where a number of drugs are detected in post-mortem tissues, it is often difficult to attribute the death to one particular drug. Reports on heroin and other opioid-related deaths in Victoria are produced on a regular basis by the Victorian Institute of Forensic Medicine (VIFM) (eg. Woods et al. 2006). Because the body rapidly converts heroin to morphine once it is administered, morphine is the drug measured toxicologically. As a result it is not possible from this data to separate cases where people have died from drug combinations containing heroin alone, those containing heroin and pharmaceutical morphine, or those containing morphine alone. However, the toxicological analysis does allow other synthetic opioids such as methadone, propoxyphene, oxycodone, etc. to be identified, along with benzodiazepines. Data from the most recent VIFM reports are presented in Table 4.2, showing the presence of drug classes in deaths containing morphine (termed heroin deaths). It shows that other synthetic opioids were found in 7 per cent of all heroin deaths over the period. The apparent increase in this proportion from 4 per cent in 2001 to 8 per cent in 2004 and 2005 is not significant. Overall the data from 2001–2005 shows that benzodiazepines are found in 60 per cent of all cases and there was an initial drop from 2001, but the proportion of deaths involving benzodiazepines has remained fairly steady since 2002 (Woods et al. 2006).

Table 4.2: Presence of other drugs in heroin (morphine)-related overdose deaths, Victoria, 2001–2005 (per cent)

	2001	2002	2003	2004	2005	Overall*
Morphine only	16	16	32	18	15	20
Morphine + benzodiazepines	71	67	48	59	54	60
Morphines + alcohol	31	24	31	36	34	31
Morphine + cannabinoids	22	12	9	11	21	15
Morphine + amphetamines	22	14	9	8	14	13
Morphine + other opioid drugs#	4	6	7	8	8	7

Notes: * Total percentage equals more than 100% as multiple combinations of other drugs were also present.
i.e. methadone, propoxyphene, oxycodone, etc.
Significant values are underlined.

Source: Woods et al. p.4.

Consistent with earlier research (eg. Darke & Zador 1996; Darke, Ross & Hall 1996; McGregor et al. 1998), Table 4.2 shows that heroin (morphine)-only overdose deaths make up a small proportion of all deaths involving heroin. The use of other central nervous system depressants, notably alcohol and benzodiazepines, is common in overdoses involving heroin. More recently, Martyres, Clode and Burns (2004) found that polydrug use was evident in 90 per cent of toxicology reports of 254 heroin-related fatal overdose cases of 15- to 24-year-olds in Victoria between 1994 and 1999.

Most methadone-related overdose deaths involve diverted methadone

With regards to methadone deaths, earlier analysis had shown that the majority of methadone-related deaths (MRDs) were for people not currently enrolled in methadone treatment. That is, they were due to the non-medical use of diverted methadone:

> Consistently and overwhelmingly, most of the recent investigations into MRDs world-wide have estimated that (where data on diversion were available) between one third and two thirds of all MRDs occurred in persons not prescribed methadone treatment…[See Table 4.3]…Data set out in this Table relate to methadone provided for treatment of heroin dependence. Where data enabled, cases of methadone prescribed for chronic pain were excluded. However, the majority of studies did not distinguish between cases of prescribed methadone for heroin dependence and chronic pain (Zador 2000, p.38)

Table 4.3: Proportion of methadone-related deaths attributed to diverted sources of methadone

Study	Location	Number of MRDs	Percentage (%) related to diversion
Baden (1970)	New York City 1967–1969	32	25%
Gardner (1970)	London 1965–1969	12	66%
Harding–Pink (1993)	Switzerland 1981–1994	18	44%
Clark et al (1995)	Sheffield UK 1991–1994	18	44%
Cairns et al (1996)	Manchester UK 1985–1994	90	36–60% *
Barret et al (1996)	Texas 1987–1992	54	85% ?†
Williamson et al (1997)	South Australia 1984–1994	21 **	57%
Drummer 1998	Victoria 1989–1998	149	19% #
Sunjic et al 1998	New South Wales 1990–1995	195 **/‡	46–63% *

Notes: * includes cases of known and probable diversion of methadone
† the authors acknowledge that this figure may be an overestimate of diversion cases because they were unable to establish what proportion of the remaining 46 cases not in MMT [methadone maintenance treatment] were recipients of prescribed methadone for pain, or in methdone programs from which they could not obtain confirmation of enrolment
** excludes cases of tablet related death
‡ includes cases of known and probable syrup forms of methadone only
# assumes cases identified under sub-heading 'number not on a MMP' [methadone maintenance program] in Table 2 of the Trigger paper were all methadone realted deaths.

Source: Zador 2000, p.39.

Buprenorphine-only overdose deaths are rare

Taken by itself the risk of overdose from oral buprenorphine use is minimal as it has a ceiling effect at about 12 mg, so doses above this last for longer but give only minimal increase in opioid effect (Clark, Lintzeris & Muhleisen 2002). This quality makes it safer than drugs like methadone that do not have a ceiling effect. This is illustrated by a case study report in which a young man consumed 35 to 40, 0.4mg tablets (35 to 40 times the prescribed dose) (Clark, Lintzeris &

Muhleisen 2002). Despite the massive dose only minimal symptoms of drowsiness were induced with no respiratory disturbances.

However, taken in combination with other central nervous system depressants, such as benzodiazepines, the risk is much higher. Reynaud et al. (1998) suggest that concomitant use of benzodiazepines and buprenorphine seems to be strongly implicated in buprenorphine overdose. The association has been reported in a number of clinical observations of respiratory depression resulting from buprenorphine taken in a therapeutic dose. The authors point out that most of the cases observed involved the intravenous use of buprenorphine. By this route, severe respiratory depression, requiring artificial ventilation has been observed with doses between 2 and 10 grams per kilogram of body weight. A single tablet of Subutex®, crushed and injected, affords a dose 10 to 50 times greater than if taken sub-lingually. Other countries have reported deaths following buprenorphine misuse (European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2005). For example, 112 cases were reported in France between 1996 and 2001, although in 2003 only eight cases were reported. In Finland, where buprenorphine is frequently abused, there were a reported 40 deaths in one year. However, more than 90 per cent of those entering treatment in Finland were injecting buprenorphine, which may account for the high number of deaths (EMCDDA 2005).

The discussion in this section has shown that both benzodiazepines and narcotic analgesics can have adverse effects when used as prescribed and under the care of a medical practitioner. But when used for non-medical purposes they are often consumed at a far higher dose, for longer periods, in combination with other drugs, and in ways that can exacerbate potential problems. As a consequence, the adverse effects of misuse of these drugs are substantial. They can include sedation contributing to confusion, memory loss and problems with driving or operating machinery; tolerance leading to escalating use and severe withdrawals when access is restricted. Overdose is probably one of the most serious consequences of pharmaceutical drug misuse. The 'Rambo effect' is one that is specific to the use of benzodiazepines, usually at high doses, and is at odds with the prescribed use to reduce anxiety and induce sleep. While benzodiazepines on their own rarely result in fatal overdose they are often involved in fatal overdoses involving heroin.

Adverse consequences of injecting diverted pharmaceutical drugs

Data presented in Chapter 3 shows that among Australian injecting drug users (IDUs) injection of diverted pharmaceuticals is commonplace. For example, 41 per cent of injecting drug users surveyed for the Illicit Drug Reporting System (IDRS) in 2005 reported injecting morphine in the preceding six months. Twenty-six per cent had injected illicit methadone, 21 per cent had injected buprenorphine, 17 per cent had injected oxycodone and 8 per cent had injected benzodiazepines (Stafford, Degenhardt, Black et al. 2006).

Included in the IDRS are questions relating to problems the respondents have experienced as a result of injecting benzodiazepines and other pharmaceutical drugs. The most commonly reported problems were difficulty in injecting, and scarring and bruising following injection. Although the proportion of IDUs who reported the injection of benzodiazepines has declined over the past five years there is still cause for concern as there are serious health problems associated with injecting drugs designed for oral use.

Also of concern in injecting drug use is the increased risk of exposure to blood borne viruses, in particular hepatitis C. The prevalence of hepatitis C among injectors is high, with numerous studies reporting that around 50 to 60 per cent of IDUs are infected (MacDonald & Zhou 2002; National Centre for HIV Epidemiology and Clinical Research 2005). HIV/AIDS among IDUs in Australia remains at less that 2 per cent, due primarily to the introduction of harm reduction measures such as needle and syringe programmes in the mid 1980s. In other countries, however, the prevalence of HIV/AIDS is considerably higher and the risk of exposure through injecting is considerable. Hepatitis B is also of concern despite the fact that there is an efficient and cost effective vaccine available to prevent the transmission of this virus (Carruthers 2003).

Injection of drugs formulated for oral administration

In a study of injection of 'non-injectables' by methadone maintenance treatment patients in Sydney, Sunjic and Howard (1996) described the method used:

> [Benzodiazepine] tablets were usually crushed, water added, and a filter used to avoid injecting the chalky material in the tablets. Capsules were pierced with a needle and contents either drawn up into a syringe or squeezed into the barrel of a syringe…
>
> The majority of respondents (76%) diluted the methadone with water prior to injection…90% used large needles (greater than 25-gauge), and 10ml barrels were most commonly used (39%) (range: 2ml–50ml). Four subjects used a 'butterfly' vein infusion set to inject the methadone.
>
> The majority of subjects injected methadone into their arms or hands. Other sites of injection included feet and legs, breasts and neck. These were usually used by respondents who had lost venous action in their arms.
>
> An equal number of respondents (35%) injected their own takeaway doses as those who brought illicit methadone. Five respondents (24%) injected their partner's or friends' takeaways (Sunjic & Howard 1996, pp.247, 248).

Physical problems from injecting pharmaceutical drugs that have been formulated for oral consumption can occur through two related processes. Firstly, either because of the way the drugs are manufactured or because of the un-sterile way in which they can be administered, there can be damage to veins, skin, muscle, major organs and other body systems as a direct result of these factors. Secondly, as a consequence of damage to the smaller, peripheral veins

they become unusable for injection so the person may go searching for larger, more central veins. Unfortunately they can miss the vein and inadvertently inject into nearby arteries or surrounding tissue. This can lead to arteries being blocked, or obstructed due to swelling, which can cut off the blood supply to parts of the body and result in tissue damage and major injuries, at its worst resulting in amputation.

As Dr Malcolm Dobbin explained:

> There are the problems arising from the illicit injection of medications that are intended for oral use. It can cause damage to blood vessels. The peripheral blood vessels can be closed down, so people then have to inject it into bigger, more central, veins, and can start injecting it into the groin or around areas where the arteries are in close proximity to the vein. It can cause inadvertent injection into the arteries as well, and you can have injection outside a vein into the tissues, which can cause inflammation and ischemia and blockage to the blood supply to certain areas. It can also cause ulceration.[80]

A case study: Temazepam injection in Australia 2000–2004[81]

Injection of the liquid contents of temazepam capsules was first documented in the United Kingdom in 1987. The first reports of serious harm began in 1988. These included gangrene from injecting into arteries, skin inflammation and ulcers, abscesses, damage to veins in the groin, along with escalating crime and black market dealing in the capsules. In 1996 the problem was finally resolved when doctors were banned from prescribing the capsules on the National Health Service (NHS) after nine years of largely unsuccessful attempts at doctor education and voluntary bans on prescribing.

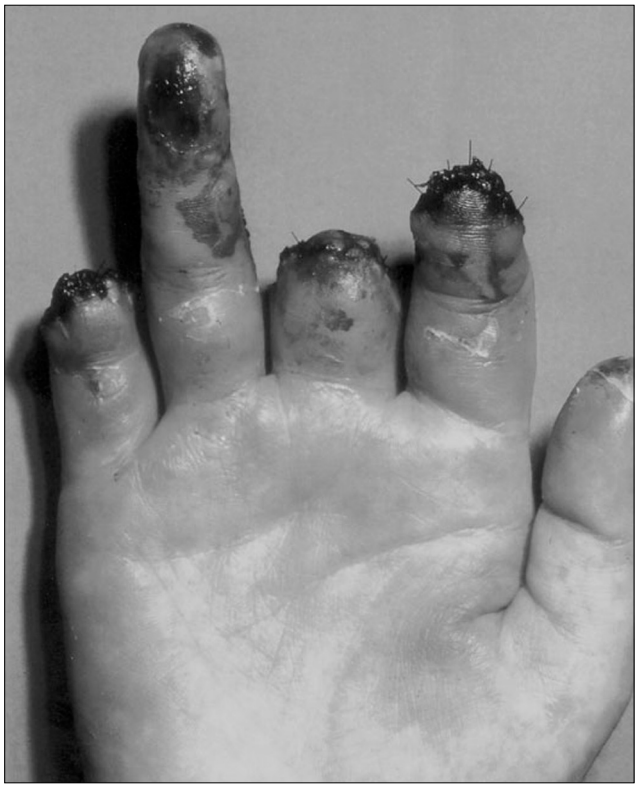
In Australia, by 1999/2000 the liquid filled gel capsules had become one of the 10 most frequently prescribed drugs on the PBS, with some 2.2 million prescriptions being written in that year. Temazepam tablets became available a few years after the gel capsules had reached the market and there was an increasing trend in their prescription. By 2001 they accounted for about 25 per cent of all PBS prescriptions in Victoria.

Use of the readily-injected liquid gel capsules was well established among injecting drug users in Victoria by 2000 (see data presented in Chapter 3), with injuries being reported in Victoria and elsewhere in Australia similar to those found in the United Kingdom. These injuries began to be documented in academic papers such as that published in the *Medical Journal of Australia* by Feeney and Gibbs (2002) describing gangrene of the fingers (Figure 4.1).

80 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, 29 May 2006.

81 This summary is largely drawn from an unpublished paper (2006a) by Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, submitted to the Drugs and Crime Prevention Committee.

Figure 4.1: Digit loss following temazepam injection



Note: Image shows patient's hand after surgical debridement and amputation of necrotic areas, three weeks after injection of temazepam.

Source: Feeney GFX et al. 2002, 'Digit loss following misuse of temazepam', *Medical Journal of Australia*, vol. 176, p.380. Copyright 2002. Reproduced with permission.

From late 2000, there was a dramatic decrease in the availability of heroin in Australia – the 'heroin drought' – with a concomitant reduction in the number of heroin-related fatal and non-fatal overdoses (in Victoria down from 339 and 312 in November 1999 and 2000 respectively, to 37 in November 2001). However, in response to the heroin shortage there was a marked increase in the injection of contents of temazepam capsules. This was associated with an increase in trafficking of capsules, pharmacy burglaries and increasing episodes of doctors being intimidated to write prescriptions for the capsules. Many of the thefts, ram raids and burglaries were exclusively targeting capsules (and not tablets) of temazepam. Capsules were being sold on the street for between $50 and $100 for a 'slab' of 25 capsules.

Authorities considered what might be the unintended adverse complications of restricting access to the capsules, which included looking at overseas experiences. In the United Kingdom and the United States temazepam capsules had not been available since 1996, and while there was a shift to injecting other benzodiazepines in the United Kingdom this shift did not include temazepam tablets. In Australia, there was also concern that any restriction would adversely

impact on patients using the drug legitimately, however this had not caused major inconvenience in the United Kingdom or the United States.

In 2001 the Victorian Department of Human Services (DHS) established a professional, and peer (IDUs, needle exchange workers and others) reference group to develop a response. This was described to the Committee by Dr Malcolm Dobbin:

> We had a Temazepam Injection Prevention Initiative in which we sent a pack with a letter from our Chief Health Officer asking prescribers not to prescribe the capsules except for long-established patients and to prescribe the tablets instead; providing them with information, with posters for their waiting rooms and scripted responses to the kinds of scams that users were using; and asking them to use our borrowed protection – that we were asking them not to do it: 'It wasn't me; it was the Department' or 'the Medical Board.'…We did decrease the supply in Victoria marginally, but it was not until it was made difficult to obtain on the PBS that there was a profound drop, so it was a regulatory change that made all the difference.[82]

In May 2002, the Australian Pharmaceutical Council recommended that temazepam gel capsules be restricted under the PBS. Prior to May 2002 temazepam (10mg tablets) and 10mg capsules (Euhypnos, Nocturne, Normison and Temaze) were subsidised by the PBS or available on private prescription. Temazepam 20mg could only be obtained through a private prescription. From 1 May 2002, temazepam 10mg capsules required an authority[83] to allow subsidy on the PBS. Temazepam 10mg tablets, 10mg capsules and 20mg capsules were still available on private prescription. These changes were designed not to restrict the use of temazepam per se, but to reduce the diversion and injection of temazepam capsules.

The effect of these restrictions was assessed by a study conducted by the National Drug and Alcohol Research Centre in Sydney, NSW (Breen, Degenhardt, Bruno et al. 2004). The study found there had been a decrease in prescriptions for temazepam 20mg capsules (393,370 prescriptions) and a corresponding increase in the prescription of temazepam 10mg tablets (368,951 prescriptions) following the policy change. Injectors continued to inject benzodiazepines and temazepam capsules and were still being prescribed the capsules even after the restrictions. The authors of the study concluded that limiting the prescription of temazepam might have reduced the injection by some IDUs but that additional strategies were needed to reduce the misuse of the drug within the study group. Approaches recommended included further restrictions on capsule prescription, further education of doctors and IDUs and examination of the prescribing practices of some doctors.

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82 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, 29 May 2006.

83 Prior approval from the Health Insurance Commission.

Following the Temazepam Injection Initiative, and partly as a result of it, in early 2004 the pharmaceutical companies voluntarily removed the temazepam products from the Australian market as a result of concerns about the above harms. This effectively ended the problem of serious vascular injury and serious tissue damage resulting from temazepam injection.

The efforts and outcomes of the temazepam project have indeed been laudable. This does not mean, however, that drugs and medicines that are not suitable for administration by injection are no longer so used. This Committee has heard concerns from numerous sources about the use of drugs such as Dozile and Unisom. According to witnesses to this Committee, these Schedule 3 drugs, which are available without prescription, are also liquid filled gel caps that can result in the same or similar problems as occurred with temazepam. For example, a submission to the Committee from the Pharmaceutical Association of Australia states:

> There are two main products on the market, Dozile® and Unisom®, which are liquid-filled capsules and used as sedatives and hypnotics.
>
> PSA is concerned about the availability and widespread abuse of liquid-filled capsules. The viscosity of the liquid when injected into veins causes considerable venous and associated tissue damage which can lead to conditions as serious as gangrene. This predominantly affects fingers, toes and limbs and gangrene of the testes has also been reported.
>
> This is an identical problem to that which led to the removal of liquid-filled temazepam capsules from the National Health Scheme some years ago.[84]

The Committee has not written about these drugs and their apparent associated problems in this Interim Report. However, it believes that sufficient concern has been expressed by people with expert knowledge in pharmacology, health prevention and medicine to warrant further exploration of the issue in any ongoing work of the Committee in this area.

Talc problems associated with injecting or intranasal use of pharmaceuticals in tablet form

People who inject diverted pharmaceutical drugs in tablet form can experience problems due to the talc incorporated in the tablets. Talc (magnesium silicate) is an inert substance most often used as a lubricating powder. It is also used in the pharmaceutical manufacturing process. When taken orally this substance is harmless but when injected or snorted can result

84 Submission of Pharmaceutical Association of Australia (Victorian Branch) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

Other concerns expressed to the Committee on this issue have come in submissions from the City of Melbourne (June 2006), the Pharmacy Board of Victoria (June 2006) and also by Dr Mike McDonough in evidence he gave to the Committee during a Public Hearing in Melbourne (June 2006).

in a condition called Talc Pulmonary Granulomatosis (TPG) (Ward et al. 2000). Minute particles of talc lodge in the lungs and create an inflammatory reaction which can result in emphysema, a condition mostly associated with cigarette smoking. Small talc particles which get passed the lung's filter action can also lodge in and block the arteries in the retina of the eye causing blindness (Raspiller et al. 2005) In a submission to the Inquiry, Dr Malcolm Dobbin described TPG in the following way.

> This is a case involving talc. If you inject intravenously, the blood goes first to the right side of the heart and then is circulated through the pulmonary artery to the lungs. Most things injected intravenously will first of all either be lodged in the lung or pass through the lung, and that is what you see here with these sorts of collections of granules in the lung. You see these talc particles surrounded by inflammatory cells. They cause granulomas, and this condition is called talc pulmonary granulomatosis. You see a talc granule there. It can then break through the pulmonary system into the general vascular system and be lodged in the lung and cause liver granulomatosis, and affect the retina and other areas through the blood supply. Once it is lodged in the lung, you have obstruction to the blood supply through the lung so that the blood pressure in the pulmonary arteries, which is usually quite low, becomes very high. You get pulmonary hypertension, and that is a potentially fatal condition. We are seeing these kinds of particles in post-mortem specimens in State Coroner's Office cases.[85]

Anex, the Australian peak body for IDUs, has also commented on the dangers associated with injecting 'non-injectable' drugs:

> Both opioid and stimulant pharmaceutical tablets that are injected carry the risk of injecting travelling particles (when not filtered adequately prior to injection). The injection of tablets containing talc has been linked to chronic inflammatory granulomas in the lung. This can lead to respiratory failure and potentially lethal pulmonary hypertension.
>
> Anecdotal evidence suggests that despite the removal of temazepam (and a reduction in the particular harms associated with injecting the gel from temazepam gel caps), clients accessing NSPs are continuing to inject pills including a variety of benzodiazepines and other pharmaceuticals. Clients are presenting with a variety of physical harms including vein damage, infection and associated health problems.[86]

85 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Melbourne, 29 May 2006.

86 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

Anex states further that it is imperative that further information, education and simple harm prevention measures are provided to drug injecting users to ensure safe injecting practices to minimise such harms.[87] The issues of education, information and harm prevention measures are discussed further in Chapter 8 of this Interim Report.

Complications associated with the injection of buprenorphine

Buprenorphine tablets are designed for sub-lingual use but, as indicated in the above discussion, are sometimes diverted for use by injection. In Australia, opiate dependent clients are required to have their buprenorphine in the presence of a pharmacist or treatment worker and wait for the three or four minutes it takes for the tablet to dissolve to reduce the likelihood that their dose will be diverted. However, some people do retain the tablets in their mouth and spit them out once they leave the pharmacy or treatment centre to be later mixed and injected. If IDUs divert buprenorphine for injection that has been in their mouth there is an increased risk of infection due to bacteria from saliva.

Jenkinson, Clark et al. (2005) have commented that following the introduction of buprenorphine as an analgesic there were reports of buprenorphine abuse, by injecting, in Australia, England, Scotland, Ireland, France, Spain, India and New Zealand. Indeed, in Scotland buprenorphine became the most commonly abused drug, resulting in its withdrawal from the market. In Ireland, a study of opiate users presenting for treatment found that, six years after buprenorphine was introduced as an analgesic, buprenorphine abuse went from 0 to 80 per cent in a 12-month period. High rates of buprenorphine injecting (71% to 79%) have also been found in samples of IDUs in France and Spain. In Australia, however, there are more stringent controls on buprenorphine with supervised dosing and no 'takeaways' (Jenkinson, Clark et al. 2005).

The findings of research by Jenkinson, Clark et al. (2005) on adverse complications of buprenorphine injecting are summarised as follows:

87 With regard to the specific issue of injecting benzodiazepines Anex states:

'The equipment requirements for those injecting benzodiazepines and a variety of pharmaceutical drugs can vary from those required for injecting opioids like heroin. In Victoria, the Department of Human Services supplies all NSP outlets with sterile needles and syringes, alcohol swabs, condoms and lubricant as well as sharps containers and paper and plastic bags for used needles and syringes. They do not however provide a variety of consumables required for the injecting process including plastic spoons, sterile water, cotton wool (for basic filtering) or tourniquets.

The provision of such equipment is one practical measure to assist in reducing the spread of blood-borne viruses such as hepatitis C amongst people who inject drugs. However, for those using benzodiazepines and other pharmaceutical tablets intravenously, a range of equipment is required including filters. The equipment required for those using tablets and pills includes:

- Sterile water
- Spoons
- Larger barrels (3ml, 5ml & 10ml)
- Cotton wool (for basic filtering)
- A variety of filters (including small, medium and large)

(Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006).

> In France, Decocq et al (1997) reported local complications after intravenous injection of dissolved buprenorphine tablets, and cases of acute hand ischemia following the intra-arterial injection of a suspension of buprenorphine have been reported (Gouny et al. 1999). Gourarier et al (1996) also described two cases of acute withdrawal in opioid-dependent patients after injection of high-dose buprenorphine.
>
> Other major, life-threatening complications have also been reported due to buprenorphine injection. Fifty-two percent of buprenorphine injectors in a study of injecting drug users attending drug abuse treatment centres in France reported medical complications of buprenorphine injection, and 33% had experienced hospitalization because of buprenorphine injecting (Varescon et al. 2002). Reports in the literature also suggest that buprenorphine injection is associated with acute hepatitis in patients infected with the hepatitis C virus (Berson et al. 2001a; 2001b; Wisniewski et al. 2001). In terms of the role of buprenorphine injection in deaths, Kintz (2001) reviewed 117 fatalities involving buprenorphine and reported that the major risk factors were injection of crushed tablets and concomitant intake of buprenorphine with benzodiazepines and neuroleptic drugs. Widespread injecting misuse of buprenorphine in France has led to calls for more stringent regulation of medical dispensation of buprenorphine (Obadia et al. 2001) (Jenkinson, Clark et al. 2005, p.198).

In Singapore, where there were over 4,000 patients on buprenorphine in 2004, Loo et al. (2005) describe and provide photographs of four recent cases of severe upper-limb complications as a result of injection, all of which had unfavourable outcomes. These photographs are reproduced here.

Figure 4.2: Complications from intravenous use of buprenorphine

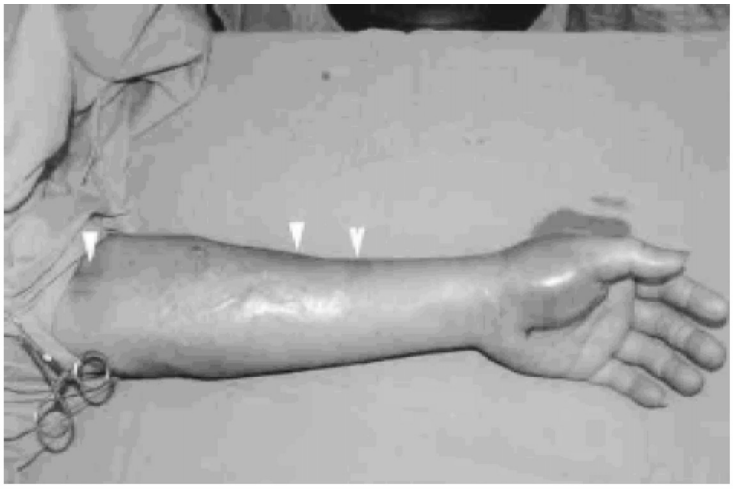


Fig. 1. Case 1, thenar intramuscular abcess. Several smaller subcutaneous abcesses are present along the line of the cephalic vein and in the cubital fossa (arrows).

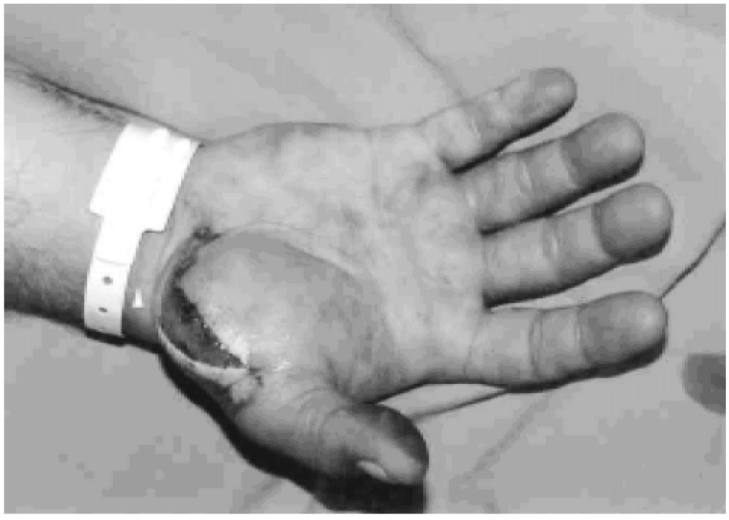


Fig. 2. Case 2, 24 hours after injecting Subutex® into the radial artery. There is fixed patchy mottling of the palmar skin similar to a "trash foot", due to micro-emboli. The tips of the thumb, index, middle and ring fingers are dusky, but the little finger is spared. This pattern may be due to an incomplete palmer arterial arch with separate supply from the ulnar artery to the little finger. Injection marks can be seen along the course of the radial artery at the wrist. Thenar fasciotomy has been performed.

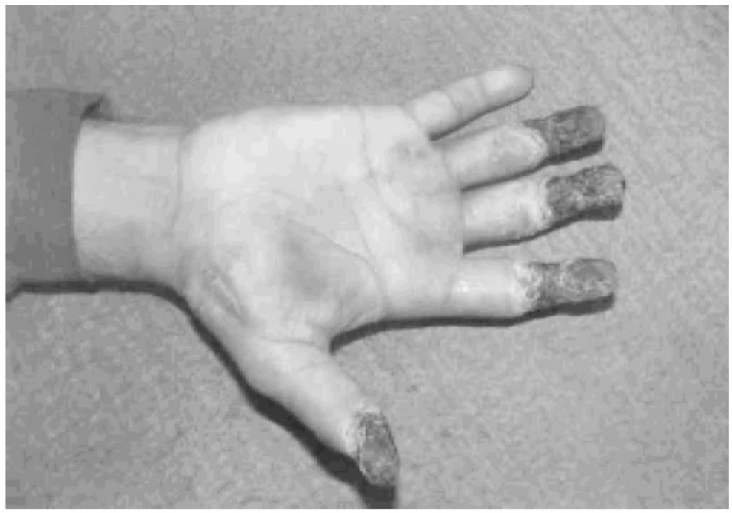


Fig. 3. Case 3, 2 weeks after injecting Subutex® into the radial artery. Dry gangrene of the tips of the thumb, index, middle and ring finger.

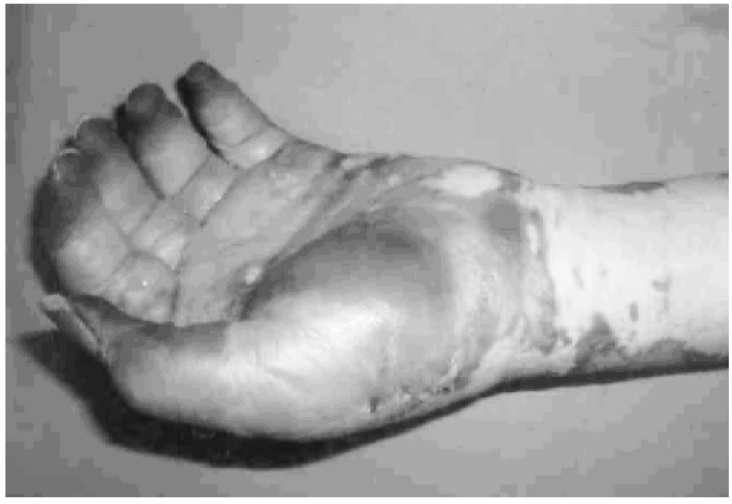


Fig. 4. Case 4, 2 months after injecting Subutex® into the brachial artery. There is wet gangrene of all the fingers, with blistering and fixed discolouration of the skin of the hand and farearm.

Source: Loo, Yam, Tan, Peng & Teoh 2005, Loo, H, Yam, A, Tan, T, Peng, Y & Teoh, L 2005, 'Severe upper limb complications from parenteral abuse of Subutex®', *Annals*, Academy of Medicine, Singapore, vol. 34, p.576. Copyright 2005. Reproduced with kind permission of the Annals of the Academy of Medicine, Singapore.

Complications from injecting diverted methadone syrup and linctus

While there may be problems with injecting diverted methadone:

> [t]here are surprisingly few reports of morbidity and toxicity from injecting methadone syrup, mixtures or linctus and the various syrup components and thickeners. Complications that have been reported to arise from injecting methadone include disseminated candidiasis, pulmonary granulomatosis subsequent to injecting methadone tablets and pulmonary talcosis, which may

> progress to severe respiratory disability or heart failure (Robinson et al. 2000, p.448).

In their small in-depth study of 19 methadone maintenance clients who diverted their methadone in Wellington New Zealand, Robinson et al. (2000) found 42 per cent injected diverted methadone three times a week or more. Injecting diverted methadone continued in 58 per cent, despite reported vascular damage resulting in difficult venous access. Their concerns about the practice included accelerating vein damage and possible toxicity of syrup additives. Most said they injected the diverted methadone to get the immediate drug effect (80%) and because of 'needle-fixation'[88] (47%) (p.447).

This section of the chapter has indicated that injecting benzodiazepines and pharmaceutical opioids can be an extremely hazardous activity. It is a practice, however, that persists despite the risks. Injection of these drugs carries the risks of transmission of blood-borne viral infections as does other drug injecting. However, there are additional risks because the pharmaceutical drugs that are most often injected are not manufactured for this purpose. This is most apparent with problems concerning injection of temazepam in gel form, the problems associated with injecting talc in crushed tablets, and injection of oral methadone syrup. Secondary problems can also occur because of the un-sterile way in which the drugs can be administered. As the peripheral veins become obstructed and the person resorts to using larger more central veins there is a greater risk of serious injury through injecting into arteries or surrounding tissues. Injuries can be severe, resulting in death of tissues and amputation in some cases.

The example of the development, consequences and responses to the injecting of temazepam gel capsules is a salutary case study in harm prevention. The injuries associated with injecting 'non injectables' are indeed horrific. Nonetheless, this well considered, evidence-based response to the problem shows how a multi faceted response across the drug-user community, government, and the pharmaceutical industry can substantially reduce the individual and community-wide adverse consequences of one kind of pharmaceutical drug misuse.

Victorian service utilisation statistics as indicators of harm

Having described the adverse effects of benzodiazepines and other pharmaceutical drugs, the question remains as to what extent these harms are realised in the Victorian community. While primary indicators of specific harms are often difficult to come by, there are a number of secondary indicators of harm from these drugs. These include ambulance attendance data, hospitalisations data, and specialised drug service data.

88 Some injecting drug users say they become addicted to the act of injecting.

In general it is straightforward to obtain data on the contribution of benzodiazepine use to demand for these services, however it is difficult to determine to what extent episodes of service are due to the adverse consequences of licit use of these drugs as prescribed or to the illicit use – that is, for non-medical purposes. However, there is more difficulty in identifying the service impacts attributable to prescription opioids. While this data is probably available from the agencies that keep records, most publicly available reports refer to 'heroin and other opioids' (eg. DHS Victoria 2006e). This is an understandable consequence of the extent to which illicit heroin use has dominated opioid misuse in Australia. However, the increasing interest in misuse of prescription opioids, reflected in the current Inquiry, points to a need for more routine reporting of the contribution of pharmaceutical opioids as a separate category of service utilisation statistics.

This section presents data on ambulance attendances, inpatient hospitalisations and specialist treatment service presentations for benzodiazepines and prescription opioids, where available. Statistics from the DirectLine telephone information and counselling service have been presented in Chapter 3 as an indirect measure of use of benzodiazepines and opioids.

Melbourne Metropolitan Ambulance Service data

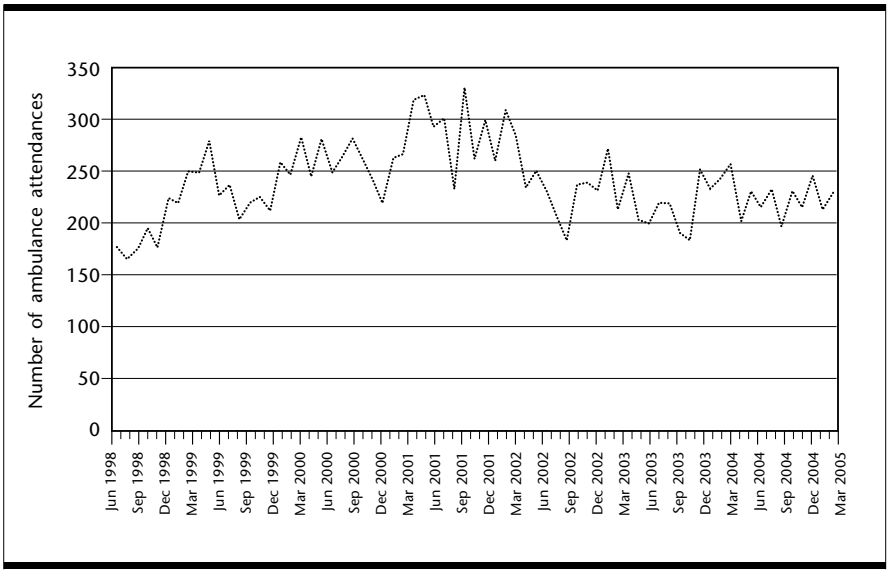
In a submission to this Inquiry, Turning Point Alcohol and Drug Centre described a joint project it is undertaking to provide drug-related analysis of ambulance records:

> The Turning Point Alcohol and Drug Centre and the Melbourne Metropolitan Ambulance Service (MAS) run a collaborative project, funded by the Department of Human Services, to collect and analyse all ambulance service records on drug-related attendances (Dietze, Cvetkovski, Rumbold & Miller, 2000). Data can be analysed and reported according to general drug classes (e.g. benzodiazepines), specific drugs (e.g. Diazepam) or combinations of drug classes/specific drugs (e.g. overdoses solely on benzodiazepines, benzodiazepines with alcohol, both benzodiazepines and prescription opioids, benzodiazepines with any other drug class etc). Data such as MAS drug attendance data can be an effective way of monitoring the harms associated with the use of particular types of drugs. The MAS drug attendance dataset can be analysed according to time (e.g. year, month, day of week, time of day), place (e.g. postcode, public/private or indoor/outdoor attendance) or characteristics of the patient (e.g. sex, age), and such data are valuable for informing a profile of the use and harms of particular types of drug use. For example, benzodiazepine-related attendances made indoors/private residence versus outdoors/public places can be used as a proxy for harms associated with the licit versus illicit use of these drugs.[89]

89 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

As an example of the kind of information available, Table 4.3 presents Turning Point data showing ambulance calls where benzodiazepines were mentioned. The number of calls peaked in 2001–2002 and was followed by a decline, which probably reflects the increased injecting of temazepam gel capsules and their subsequent decline as restrictions described elsewhere in this chapter came into effect. No data was included in the Turning Point submission on ambulance calls involving prescription opioids, although the above quotation indicates that such data should be able to be extracted from their joint database.

Figure 4.3: Monthly benzodiazepine-related ambulance attendances, Melbourne, June 1998 to March 2005

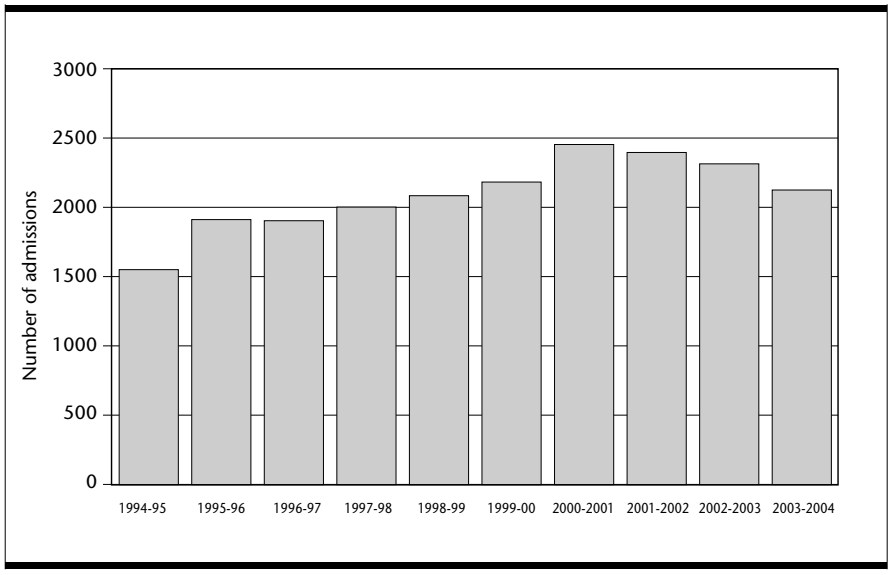


Source: Submission to the Inquiry by Turning Point Alcohol and Drug Centre, May 2006.

Hospitalisations

The Department of Human Services (2006e) estimated that in Victoria there were 2,128 inpatient admissions attributable to consumption of benzodiazepines and other sedatives and hypnotics, resulting in 4,487 bed days in the 2003/04 financial year. This comprised some 29 per cent of all drug-related hospitalisations, and 18 per cent of all drug-related bed days, excluding alcohol and tobacco. Benzodiazepines and other sedatives and hypnotics were responsible for less than 0.11 per cent of all hospitalisations in Victoria in that period. Figure 4.4 shows that since 1994 there has been a slow increase in hospital admissions for these drugs in Victoria up until 2001, then a gradual decline thereafter. Intoxications and poisonings accounted for 93 per cent of admissions and 77 per cent of hospital bed days in Victoria during the 2003/04 financial year (DHS 2006e). Data on opioid–related hospitalisations is not included here as those reported in publicly available documents include heroin-related admissions in this category.

Figure 4.4: Benzodiazepine[90]-related inpatient hospitalisations, Victoria, 1993–94 to 2003–04



Source: Department of Human Services (DHS) Victoria 2006e, p.61.

Specialist alcohol and drug treatment service data

Specialist drug service data in Victoria is collated in the Alcohol and Drug Information System (ADIS). Community agencies are funded by the Victorian DHS to provide specialist alcohol and drug treatment services to clients and are required to collect basic client data which is collated by ADIS (DHS 2006e). In the 2003–04 financial year benzodiazepines were identified as the primary drug of concern in 1,144 (2%) courses of treatment undertaken by specialist drug treatment agencies, 56 per cent of which were treatment of female clients (DHS 2006e). In the same financial year opioids other than heroin were identified as the primary drug of concern for 1,820 (2%) courses of treatment at specialist drug agencies in Victoria. The submission from Turning Point Alcohol and Drug Centre observed that the Victorian DHS, in conjunction with the Ministerial Council on Drug Strategy (MCDS), recently called for tenders to study the nature, extent and adverse consequences of pharmaceutical drug misuse among patients presenting for treatment at drug and alcohol treatment agencies across the country.[91] This project should provide useful data for the Drugs and Crime Prevention Committee's full Inquiry.

Summary

This section shows that while there are some secondary data available on service utilisation as indicators of harm in the Victorian community, extraction of this

90 This includes 166 cases of other sedative/hypnotic drugs (DHS 2006e).

91 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

data from publicly available sources is difficult, especially for the pharmaceutical opioids. What data is available however, shows that benzodiazepines comprise a small proportion of hospitalisations and specialist drug treatment episodes. Trends in both ambulance attendances and hospital admissions appear to reflect trends in patterns of drug availability and use, such as the impact of the heroin drought and the measures put in place to restrict the availability of readily-injectable gel-cap formulations of temazepam.

Conclusion

When most people think of drug-related harm they tend to think of harm due to illegal drugs. Over the last 20 or so years there has been a concerted push to have the wider community recognise the adverse effects of the legal, and most widely-used drugs, namely alcohol and tobacco. But prescription drugs, while of great benefit to many ill people in the community, are also increasingly being misused and associated with serious harms. Indeed, as efforts to disrupt illicit drug markets and further restrict their use continue, we can expect that the non-medical use of diverted pharmaceuticals will grow. This should be of concern to us as a community, not least because evidence suggests that pharmaceutical drug misuse may be an early pathway into misuse of a range of drugs, but also because the misuse of these drugs in themselves pose major risks to health and wellbeing at an individual, family and community level.

For many in the community the misuse of prescription drugs and the associated adverse health consequences has been happening 'beneath the radar'. This chapter has attempted to give an insight into some of the adverse consequences of pharmaceutical drug misuse. This form of drug abuse can have very serious consequences and is worthy of further attention by policymakers, bureaucrats, health service providers, drug users and the broader community. However, the account given here has been relatively cursory. There is more to learn about the consequences of pharmaceutical drugs misuse, not just for benzodiazepines and opioids but also for other drugs of abuse such as antidepressants, steroids, psychostimulants, and the large number of over-the-counter medications which themselves may be responsible for greater harm due to their greater availability and more widespread use. There are also lessons to be learned about how these trends in use and consequent harms can be identified and prevented.

Questions for further consideration

Are the adverse effects of benzodiazepines and other pharmaceutical drugs when they are used legitimately under medical supervision sufficiently understood and managed in the community?

What are the secondary costs of pharmaceutical drug misuse in Australia with regards to health and crime indicators?

To what extent does pharmaceutical drug misuse take a social and emotional toll on individuals, families and communities from the Australian and Victorian experience?

The serious injuries as a result of injecting the liquid contents of temazepam gel capsules lead to these being removed from sale. To what extent are drug injectors injecting other liquid-filled capsules used as sedatives and hypnotics? Is this associated with similar kinds of harms as temazepam injecting? If so, what regulatory, educational and other responses have been made and to what extent have they been effective?

What lessons can be learned from the responses to the Australian experience with adverse effects due to injecting liquid contents of temazepam gel capsules which can inform strategies to prevent similar problems with misuse of pharmaceutical drugs?

With increasing use of buprenorphine as a treatment for opioid dependence, it is observable that increasing numbers of injecting drug users inject this drug. What have been the adverse effects of this? Are there any indications of the kind of harm associated with buprenorphine injecting that have been seen in other countries? What have been the prevention strategies employed and to what extent have they been successful?

To what extent has the introduction of Suboxone®, a combination of buprenorphine and naloxone designed to deter injection, reduced the diversion and injection of buprenorphine? Have there been any unintended adverse consequences of this change.

Are publicly available health service statistics adequate to provide secondary indicators of the levels of community harm associated with benzodiazepine and prescription opioids adequate? How can these statistics be improved to make them more useful?

5. Misuse of Benzodiazepines and Other Pharmaceutical Drugs – Reasons for Use and Methods of Access

Introduction

This chapter complements the statistical analysis presented in Chapter 3 on prevalence of use by providing a descriptive overview of the reasons why people use benzodiazepines and narcotic analgesics for non-medical purposes. It also describes how they access these drugs. Unfortunately, there is a relative dearth of information and research giving insights from a drug user perspective on the culture of pharmaceutical drug misuse. Certainly this is the case compared to other licit drugs such as alcohol and illicit drugs such as heroin and amphetamines.[92] As a consequence, while some user accounts have been included in this chapter where they are available, most of the information presented here is based on research and accounts from service providers' perspectives. While it is likely that accounts of pharmaceutical drug misuse will be embedded in accounts of polydrug use, there appears to be a need for in-depth qualitative research of non-medical use of prescription drugs from a user's perspective, both in Victoria and nationally. Victorian researchers have also made this observation, for example Jenkinson and O'Keefe (2006). Research of this nature will be invaluable in informing regulatory, preventive, and treatment responses to this growing phenomenon.

The chapter begins with a summary of reasons for non-medical use of benzodiazepines and narcotic analgesics. There are wide-ranging reasons as to why people may use prescription drugs for illegitimate purposes.[93] This section,

92 See for example other reports tabled by the Drugs and Crime Prevention Committee such as the *Final Report of the Inquiry into Amphetamine and 'Party Drug' Use in Victoria* (Drugs and Crime Prevention Committee 2004) and the *Final Report of the Inquiry into Strategies to Reduce Harmful Alcohol Consumption in Victoria* (Drugs and Crime Prevention Committee 2006). Both these reports drew on a voluminous research literature discussing the cultural aspects of drug use and abuse.

93 See Chapters 1 and 2 of this Interim Report.

however, will primarily focus on the main reasons illicit drug users self-administer benzodiazepines and prescription narcotics. The use of short-acting benzodiazepines such as flunitrazepam (eg. Rohypnol®) as a 'date rape' drug will not be addressed here because this has received recent extensive coverage elsewhere (Taylor, Prichard & Charlton 2004). This is particularly the case given that the motivation for use in this context is to take advantage of another person rather than to experience the drugs' psychoactive effects.

As demonstrated in Chapter 3, injecting drug users (IDUs) are an important group in understanding non-medical use of these drugs. Consequently, this section also includes an account of patterns of use by current IDUs in Victoria studied as part of the Illicit Drug reporting System (IDRS) (Jenkinson & O'Keefe 2006). The section on reasons for use concludes with an exploration of claims of a new phenomenon of pharmaceutical drug misuse by adolescents in the United States termed 'pharming parties'.

The next section of the chapter provides accounts of strategies employed by non-medical users to acquire pharmaceutical drugs. Strategies addressed include: 'doctor shopping'; the use of forged, stolen or altered prescriptions; acquisition from friends and family; diversion by pharmacy staff and other health care workers; retail theft; theft from pharmaceutical suppliers and wholesalers; access from criminals and other drug users; and finally, the emerging trend of access via the Internet.

The chapter concludes with a case example of the misuse of OxyContin® in the United States, which aims to provide some background to the statistics on increasing availability and misuse of this drug in both the United States and Australia, as outlined in Chapter 3.

Reasons and patterns of use

As indicated above, the reasons why prescription drugs may be used illegitimately and the patterns of their use are many and varied.

Lloyd, Guibert & Bell (2000), for example, note that there are many reasons people seek to obtain pharmaceutical drugs without legitimate prescription. These include those who:

- are not prescribed as much of a pharmaceutical drug as they want and/or think they need and thus seek to continue or augment the medication prescribed for them;
- have become habituated or addicted to a drug that has been previously prescribed for them and seek further quantities of the drug;
- abuse illicit drugs and use pharmaceutical drugs to counteract or mitigate their effect; and
- use them as a source of revenue by selling them to the illicit market (Lloyd, Guibert & Bell 2000, p.57).

Consideration of the reasons and patterns of non-medical use of pharmaceutical drugs at an individual level need to be understood in terms of the macro factors that may influence this trend, Thus:

> Factors that may contribute to the growth of diverted pharmaceutical markets include: (1) a sizeable licit supply of prescription and controlled medications; (2) the routine prescription of benzodiazepines and opioids to alleviate drug-related symptoms, such as anxiety, insomnia or withdrawal for people who inject illicit drugs; (3) the inherent instability of illicit drug markets, compared to the constant availability of pharmaceuticals; (4) the potential profits from selling prescription drugs because of their relatively low pharmacy dispensed cost; (5) the reduced legal risks in supplying and possessing prescription drugs compared to illicit drugs; and (6) the impact of new technology in facilitating prescription fraud (Topp 2006, p.6).

Reasons for use

The demand for pharmaceutical drugs for illicit use is dynamic, varying from time to time and location to location. Fountain and colleagues (2000) describe such a phenomenon in their account of the London drug scene:

> As the supply of diverted prescription drugs differs between markets, so does demand. In some markets, diverted prescription drugs are not a marketable commodity (Whynes et al., 1989), while others trade primarily in these substances (Edmunds et al., 1996; Fountain et al., 1996). Contradictory reasons for demand have been reported, and there have been calls for further research into this issue (Ruben & Morrison, 1992; Strang et al., 1993; Darke, 1994). Patterns of use of diverted prescription drugs range from regular and heavy use by polydrug using opiate addicts to occasional use by so called 'recreational' drug users. Purchases of diverted drugs are not necessarily made on a regular basis. The diverted drug can be a 'treat', for use as an experiment, or in an emergency such as buying oral methadone to avoid withdrawal symptoms when no heroin is available (Dale & Jones, 1992; Fountain et al., 1996). Thus the amounts of substances purchased from the illicit market vary from, for example, a single dose of methadone occasionally to 2 weeks' supply regularly, or from a couple of benzodiazepine tablets as a 'one-off' experiment to 20 tablets every day. Some buyers are discerning about the drugs they buy, others are less particular. In addition, an individual is likely to change his or her reasons for purchasing prescription drugs according to his or her current drug-using pattern, treatment status and financial situation (Fountain et al. 2000, p.398).

Factors such as the drug user's location are also a relevant consideration. For example Dr Rodger Brough, a specialist drug and alcohol doctor working in rural Victoria, observed that:

> My impression is that this issue assumes greater relative significance the further away from Melbourne you go...The explanation for this phenomena I suspect, relates to the fact that the further the users are away from Melbourne, the less

> viable it is for them to spend the time and effort travelling to and from Melbourne to buy heroin, particularly when they are at the end of that distribution chain, with [a] relatively 'poor quality' drug.[94]

Having given an overview of the general factors that may explain an individual's non-medical abuse of pharmaceutical drugs, the following section will outline some more detailed and specific reasons for such abuse. These include but are not restricted to:

- Dependence occurring as a result of medical treatment (iatrogenic dependence);
- Self medication;
- Dealing with withdrawal symptoms;
- Drug substitution,
- Enhancement of other drug use;
- Use by clients in opiate treatment;
- Use as a currency by street users;
- Having a preference for pharmaceutical over street drugs; and
- Prescription drug use as 'recreational culture'.

Each of these factors is discussed briefly in turn.

Iatrogenic dependence

People can seek pharmaceutical narcotics and benzodiazepines because they have become dependent on a drug they were prescribed through their treatment for a previous or continuing medical condition. A good example of this is chronic pain patients who may become opioid dependent as a result of long periods of consuming prescribed or over-the-counter analgesics. Another example is long-term users of benzodiazepines. As noted by the support agency TRANX in their submission to the Inquiry, it has been known for many years that use of benzodiazepines at the appropriate prescribed dose for more than a few weeks can result in a dependence syndrome and serious physical complications associated with withdrawal.

> In the case of the benzodiazepines, significant harm has been and continues to be caused to people taking these drugs in prescribed doses, but for inappropriately long periods of time. Many of these people have taken doses within the recommended daily dose limit, have only seen one GP and have taken the drugs as advised by their medical practitioner. It may be more

94 Submission of Dr Rodger Brough, WRAD Centre in Warrnambool, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

> appropriate to describe the drugs as being "mis-prescribed" rather than 'misused'.[95]

Many iatrogenic patients can develop complex and difficult problems associated with their drug seeking, as noted in a case study provided in a submission from the Interhospital Liaison Group, Southern Health, Dandenong Hospital:

> A 59 year old lady presented to hospital for management anaemia. She was living alone, at home, having separated from her husband and was estranged from her children. She was unemployed. Over the previous 3 months, she had become increasingly short of breath, had reduced exercise tolerance and had multiple episodes of hyperventilation, anxiety and tremulousness. She was found to have a low haemoglobin but when she presented for further investigations, she was found to be too intoxicated with alcohol for a gastroscopy to be performed safely.
>
> She had a past history of: falls resulting in fractures to her left arm; suicide attempts by overdose; and social isolation. She had developed a significant alcohol dependence which she described as a response to receiving inadequate benzodiazepine dosage. A history of chronic benzodiazepine dependence emerged. She had first been prescribed barbiturates when 14 years of age, in response to symptoms of agoraphobia. Subsequently, she had used benzodiazepines continually, escalating in doses up to 24mg of alprazolam per day (equivalent to 240mg diazepam per day). When her doses were reduced, she described increasing social dysfunction and limitation of daily activities due to anxiety. She had developed a significant pattern of helpless and hopeless psychological themes and fitted into the diagnostic criteria for borderline personality disorder. There had been multiple instances where clinicians had refused to prescribe her high doses and she had experienced prolonged withdrawals. She described frequenting up to 7 General Practitioners concurrently to gain a supply of benzodiazepines. Her dissatisfaction with treatment and ongoing poor response to medications resulted in her drinking heavily for 4 years. She attended a residential detox. unit for alcohol dependence but started drinking soon after leaving there.[96]

Self harm and suicidal ideation

An account of people, predominantly women, who may use prescription drugs in an attempt to end their own lives has already been given in Chapter 3. This was in the context of research conducted on prescription drug abuse in the north east Melbourne municipalities of Moreland and Darebin. During the course of that research it was found that:

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95 Submission of Ms Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

96 Submission of the Interhospital Liaison Group, Southern Health, Dandenong Hospital, Melbourne, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

> Despite the taboo topic of drug overdose, and community silence on suicidal ideation, the researcher was able to make contact with a number of women who had overdosed on medications. The common themes for the majority of women contacted were a history of sexual abuse and/or family violence.[97]

In particular women subject to depression and anxiety for whom benzodiazepines had been prescribed did not necessarily understand that the effect of such medications could be to exacerbate rather than relieve their illnesses:

> This is not always clear to the people taking the medications, who often feel that the rise in anxiety and depression is symptomatic of their own inability to cope and not an impact of the medication itself…[98]

This could result in a dangerous cycle whereby long term prescribing to alleviate problems associated with illnesses such as depression could eventually lead to patterns of suicidal ideation. Whilst such localised research is not necessarily indicative of a more widespread connection between [long term] prescribing of benzodiazepines and suicide attempts, it is an issue that could certainly be the subject of further and more generalised research.

Self-medication

People can seek pharmaceutical drugs, especially benzodiazepines and narcotic analgesics, in order to quell the pain of previous physical or emotional trauma, or treatment of an underlying drug dependency problem. With regards to the latter, Fountain and colleagues (2000) observe:

> It has been suggested that some of those buying diverted prescription drugs – particularly methadone – are engaged in self treatment (Langrod, Galanter & Lowinson 1974; Spunt et al., 1986; Gossop, Battersby & Strang 1991; Dale & Jones 1992), and that the benefits of prescription drugs are therefore reaching an out-of-treatment population. However, 'self-treatment' suggests that users are mimicking the therapeutically based decisions of treatment agencies. The combinations and supratherapeutic amounts of drugs used by some who buy prescription drugs on the illicit market are not generally purchased with such therapeutic objectives, and would not be available to them in these forms and doses via legitimate treatment sources (Ruben & Morrison 1992; Seivewright & Dougal, 1993; Strang et al., 1993). Nevertheless, some users of diverted prescription drugs have assimilated the harm reduction advice emanating from drug treatment services and disseminated by the drug users' grapevine. Ironically, the knowledge that illicit drugs and injecting are dangerous probably increases the demand for the 'safer' prescription drugs for injection (Edmunds et al., 1996; Fountain et al., 1996), even though there may be additional

97 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and other Pharmaceutical Drugs in Victoria, July 2006.

98 Ibid.

> dangers from the crushing and injecting of tablets meant only for oral use (Strang et al., 1998; Department of Health 1999) (Fountain et al. 2000, p.398).

The research conducted into prescription drug abuse by people within the Darebin and Moreland communities referred to above also indicates that for many people, particularly women, benzodiazepines were indeed a major coping mechanism for dealing with pain and trauma:

> The overwhelming reasons indicated for women using benzodiazepines – in conjunction with alcohol or marijuana – was to avoid flashbacks from childhood sexual abuse, and adult pain from domestic violence:
>
> > "My own use of sleeping pills increased over a period of time because I became dependent on them to actually get to sleep. The same applied to antidepressants. My alcohol intake increased from the age of 14 up until I was 39 years old. This was due to: sexual abuse as a child; an abusive relationship; divorce; being a sole parent; often not coping with life in general. The tablets and alcohol were used to block out the hurt."
> >
> > — Participant in research discussion group[99]

In the context of young people, the Youth Substance Abuse Service (YSAS) addressed the issue of drug seeking in order to deal with past emotional trauma in their submission to the Inquiry:

> Benzodiazepine use is common among people with a history of early life or developmental trauma (Sansone 2000). … Sansone [observes] that benzodiazepine use is associated with some aspects of trauma and noted the possibility that cognitive characteristics of benzodiazepines may offer a degree of protection from re-experiencing previous traumas.[100]

YSAS noted that the majority of clients they engage with have traumatic backgrounds and benzodiazepines offer a way of addressing the emotional turmoil in their lives.

> The 'typical' young person accessing the services provided by YSAS has experienced multiple adverse events in his or her life, apart from and preceding those associated with their alcohol and/or drug use. The majority of these young people have experienced significant levels of trauma and abuse during their childhood and adolescence. Children who have been exposed to overwhelmingly negative early life experiences suffer from a 're-setting' of their arousal baseline, so that even when no threat is present they remain in a state of physiological alarm. This makes them more 'reactive', increasing the likelihood they will be pushed into a state of terror by quite minor stressors. These changes in arousal levels as a result of abuse and neglect play a major

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99 Cited in Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and other Pharmaceutical Drugs in Victoria, July 2006.

100 Submission of the Youth Substance Abuse Service (YSAS) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

> role in the behavioural problems associated with such young people. For these young people drugs provide an escape from unbearable feelings.[101]

An example of people using diverted pharmaceutical drugs to treat their own dependency problem was given by the Western Region Health Centre's submission to the Inquiry:

> [Benzodiazepines are]...commonly used by people who inject drugs as a way to self-manage a home-detoxification. Pharmaceuticals required for detox management may be acquired through the 'black market' or through consultation with a GP. Many people will prefer to access benzodiazepines for a home detox through the 'black market' for fear of discrimination and judgement from a GP, fear of being seen (and recorded by the Government) as a 'doctor shopper' and the ramifications of such. It must be remembered that relapse is not uncommon for a person who has been injecting drugs. This practice of self managed home detox ensures privacy for the person/s concerned.[102]

Dealing with withdrawal symptoms

Benzodiazepines have long been used by heroin users to help manage the discomfort of opiate withdrawal. This is also described in the submission to the Inquiry by the Western Region Health Centre:

> Benzodiazepines alleviate some withdrawal symptoms including insomnia and anxiety. Due to the difficulties in maintaining a consistent heroin supply, heroin withdrawal can be a regular occurrence. Therefore many people are using benzodiazepines frequently to maintain a level of drug intoxication and to prevent drug withdrawal. In these circumstances, people are topping up with benzodiazepines whenever they are having trouble accessing heroin.[103]

Drug substitution

The use of benzodiazepines and pharmaceutical opioids to stave off withdrawal symptoms in the short term is one thing, but when there are longer-term declines in the market availability of a drug , such as happened with the so-called 'heroin drought' in Australia, there can be a more large-scale and sustained shift toward substitution of pharmaceutical drugs. For example, subsequent to the onset of Australia's 'heroin drought', there was a dramatic

101 Submission of the Youth Substance Abuse Service (YSAS) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

102 Submission of the Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

103 Submission of the Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

increase in benzodiazepine use by IDUs surveyed as part of the IDRS, and a spike in temazepam gel capsule prescriptions (Degenhardt et al. 2005).[104]

The change in the Victorian drug market and the increased use of benzodiazepines is reflected in the YSAS submission to the Inquiry:

> Use of benzodiazepines has increased as access to heroin has declined. There are very few pure heroin users now although that is the preferred drug. The opiate dependents use either a mix of non-prescribed buprenorphine in conjunction with benzodiazepines or prescribed methadone with benzodiazepines.[105]

Enhancement of other drug use

Drug users often use pharmaceuticals to increase the effects of other drugs that they are taking, as Dr Mike McDonough described clearly in evidence to the Inquiry:

> In particular, we know heroin users commonly use benzodiazepines in conjunction with their heroin use and sometimes inject or take benzodiazepines orally around the time of injection. This is generally to augment or facilitate or increase the opiate effect – "increase the rush", or the pleasurable effect – of the drugs. If you have been tolerant and you are dependent on a drug for a long period of time and the street purity is fluctuating a lot, another way you can boost the effect is take another drug that helps facilitate or augment the effects of the drug that you are taking. That is a common reason that heroin addicts go for benzodiazepines and they are easily available, certainly under Medicare. You can go to the local doctor and get a PBS prescription and it does not cost you much money, so comparative to illicit drugs they are very easily available.[106]

Use of benzodiazepines and other pharmaceutical drugs by opioid treatment clients

Opiate dependent clients undergoing pharmacological treatment with methadone, buprenorphine, naltrexone or other medications sometimes use benzodiazepines or other pharmaceutical drugs in order to get intoxicated.

Methadone, which is used for the treatment of opiate dependence, works by flooding the opioid receptor cells in the patient's brains with a long-acting opioid. After a stable dose is reached the patient becomes tolerant to the intoxicating effect. This tolerance means they are effectively unable to get high

104 Such a phenomenon, although evident in Victoria, was not as noticeable in other jurisdictions (Degenhardt et al. 2005).

105 Quote from Youth Substance Abuse Service Outreach Manager in submission of the Youth Substance Abuse Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

106 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 20 June 2006.

on heroin or other opioids. This is referred to as the 'blockade' effect of methadone. As a consequence these clients must use non-opioid drugs such as benzodiazepines to get intoxicated. Consequently, methadone clients have long been known to have high rates of current benzodiazepine use. For example Darke et al. (1993) found 37 per cent of methadone maintenance clients reported use in the previous month, with 11 per cent of clients using five or more pills per day. Furthermore, Swensen et al. (1993) found rates of benzodiazepine use were higher for those on higher doses of methadone, yet other opioid use was higher among those at lower doses of methadone. This was presumably because at higher doses clients could not get intoxicated on opioids due to the 'blockade effect' of a high methadone dose, but could get 'high' on benzodiazepines. Patients on lower methadone doses, however, could still get intoxicated by taking heroin or other opioids in addition to their methadone dose. More recently, reviews of research on patients in methadone maintenance programmes reported current use of benzodiazepines ranging from 10.5 to 70.4 per cent (Weizman, Glekopf, Melamed et al. 2002).

A submission from the Western Region Health Centre described this use of benzodiazepines by treatment clients as follows:

> A significant number of people on pharmacotherapies (opiate substitution therapy i.e. methadone) also take benzodiazepines. Once stable on a pharmacotherapy program the person isn't getting the sedated effect from heroin anymore, and may want to abstain from using heroin, but still psychologically seeks some form of sedation. For some people, using benzodiazepines is a way of getting intoxicated without using heroin.[107]

Buprenorphine has a greater affinity for the (Mu) opiate receptors in the brain than does the naltrexone molecule (Law et al. 2004). Naltrexone is used as a blocking agent to prevent opioids having an effect. As a result, it appears that people on naltrexone can become intoxicated on buprenorphine, while they cannot on other opioids such as heroin. Consequently there have been anecdotal reports of diverted buprenorphine being used by naltrexone patients to get intoxicated.[108]

Use as a currency by street and other users

One of the reasons people seek pharmaceutical drugs is to sell them or trade them on the illicit market. Someone accessing prescription medicine on the pharmaceutical benefits scheme (PBS), or even a private prescription, can make a substantial sum selling his or her medicine. The Registrar of the Pharmacy Board of Victoria explained this when he gave evidence to the Inquiry:

107 Submission of the Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

108 Personal communication to the consultant from Dr Noel Plumley, Senior Medical Officer, Drug and Alcohol Office, Department of Health, Western Australia, 28 July 2006.

> The trouble is that morphine is worth about $1 a milligram on the street at the moment. That means sustained release morphine tablets of 60 milligrams, a packet of 20, would be worth $1,200, yet [people] might obtain this for $3.70 because most of them have a pension card, so there is a big profit incentive…[People] from Horsham are alleged to go to Ballarat to see medical practitioners there, have them dispensed in Ballarat, take them back to sell in Horsham.[109]

Some alcoholic patients who are often prescribed benzodiazepines to aid with sleep and withdrawal problems are also known to sell their medications to others in order to buy alcohol (Fountain et al. 2000). For example:

> We have had anecdotal reports of 'alcoholic' patients selling diazepam to get money to buy alcohol.[110]

Even more alarming in some respects are anecdotal accounts of terminally ill patients trading their legitimately prescribed pain relief. Dr Mike McDonough of Western Hospital testified to this phenomenon when he gave evidence to the Committee:

> There is a problem, albeit very uncommon, but it is sad to say that some cancer patients have been found to be sources of diverted drugs. That is, they have perhaps sold and made some money from having been supplied more than perhaps they needed. There may have even been cases when there has been a death within a family, with the cancer patient leaving behind large quantities of narcotics [and someone has traded or on-sold these drugs]. So with patients who are in the pain management care of an oncologist, sometimes the way they manage their medication may need to be monitored very carefully.[111]

A preference for pharmaceutical over illicit street drugs

It is not hard to imagine why some users would prefer pharmaceutical drugs rather than illicit drugs bought on the street.

> The impurity and cost of illicit drugs means that some prefer prescription drugs to obtain these effects (Fountain et al. 1996). It has been suggested that benzodiazepines and buprenorphine (Temgesic) are consequently taking the place of heroin as the preferred drug (Sakol, Stark & Sykes 1989; Hammersley, Lavelle & Forsyth 1990; Klee et al. 1990). An additional significant attraction of prescription drugs to the purchaser is that they are manufactured in standard doses and are recognizable (Fountain et al. 2000, p.399).

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109 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, 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 Hearing, Melbourne, 19 June 2006.

110 Submission of Dr Rodger Brough, WRAD Centre in Warrnambool, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

111 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 13 July 2006.

Another reason for preferring diverted pharmaceuticals rather than getting them legitimately on prescription can be a desire to keep one's distance from the official treatment system, as explained by Fountain and colleagues (2000):

> There are several reasons why those who are drug-dependent and buy diverted prescription drugs do not arrange their own prescriptions, including an unwillingness – especially of women with children – to submit to official attention, and that previous treatment episodes have left them disillusioned with services (McKeganey 1988; Sheehan, Oppenheimer & Taylor 1988; Stimson et al. 1995; Department of Health 1996; Powis et al., 1996) (Fountain et al. 2000, p.398).

Anecdotal evidence also suggests that among certain groups in the population, particularly women, reliance on prescription drugs may have less 'stigma' attached to it than dependence on other (illicit) drugs. If such drugs are legal and particularly if they come from a legitimate source such as a general practitioner then *ipso facto* the 'respectable' people who use them cannot be 'drug addicts'. For some people this may be the self-justification for the use and abuse of these drugs.[112] In evidence to the Inquiry a representative of the Victorian Inter-Hospital Group confirmed this and explained the difficulty such a belief or attitude creates in terms of treatment:

> One of the issues that we see, particularly in the hospitals and it is reflected in the treatment services, is that it is across all socioeconomic strata. It is not just typical drug users. In fact, they are probably easier to treat. It is the middle-class, middle-age women who come in with benzo abuse and trying to help them see that they have a problem – they usually hang on to, 'But my doctor gave them to me' – that they are in fact addicted, and how you treat them becomes problematic because they are from a different mindset.[113]

Users of pharmaceutical drugs are also less likely to be subject to police attention and if a person does have prescription drugs in their possession[114] it may not be entirely clear to a police officer whether that person is breaking the law in doing so. Related to this, Fountain and colleagues (2000) noted:

> The legality of ownership of prescription drugs facilitates the operation of market-places where they are traded. Potential buyers and sellers can linger with impunity until the point of sale. It has been reported that the police rarely discover diverted prescription drugs because distribution is contained within networks of drug users trading in personal prescriptions (Parker & Kirby, 1996) (Fountain et al. 2000, p.395).

112 See for example, discussion in the submission of TRANX to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

113 Ms Ros Burnett, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

114 For a discussion of the law with regard to (pharmaceutical) drugs, see Chapter 6.

Prescription drug use as recreational culture – 'Pharming Parties' – New youth drug use phenomenon or media beat-up?

Drug use or abuse as part of a cultural or tribal phenomenon is well established (Moore 2002; Measham, Aldridge & Parker 2001, Drugs and Crime Prevention Committee 2004, 2006). Whether this pertains to the injection of heroin on the street, the consumption of alcohol on Friday night as a post-work relaxant, or the ingestion of ecstasy at raves and dance parties, the setting or context of drug use is as important as the drug itself (Zinberg 1984).

Bearing this in mind, claims of a relatively new phenomenon of pharmaceutical drug use by young people have appeared in the popular press in the United States. So-called 'pharming parties' are described as:

> …get-togethers where prescription drugs are exchanged. These parties, while not necessarily devoted to illegal substances, are meeting places to use prescription drugs in order to become intoxicated. Such parties are generally an abuse of prescription medication, especially when involving teenagers, who often participate.
>
> Analgesics (such as OxyContin or Vicodin), anti anxiety medicines (Valium or Xanax), or attention-deficit disorder drugs (Ritalin or Adderall) are common fare. While improper use of pain medication is dangerous, such drugs are highly prized for the level of intoxication they provide. Pills are generally acquired via online pharmacies, which don't require prescriptions. As well, participants will use legitimately prescribed medication (and may feign or exaggerate symptoms in order to be given further prescriptions); trading does occur, however (Wikipedia – the online Encyclopaedia, accessed 29/07/06).

An article in *TIME Magazine* (Banta 2005), following up on the release of the National Centre on Addiction and Substance Abuse (CASA) (2005) report *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.*, gave the following account of 'pharming parties':

> In the basement of a Cape Cod [house] on a suburban street in northern New Jersey, a teenage boy turns to a friend and asks impatiently, "What did you get? I'll give you some of this" – indicating a bottle of Ritalin stuffed into the front pocket of his backpack– "for some of that painkiller". As a rap song plays just loud enough not to disturb the neighbors, his friend eyes the bottle suspiciously. "Is this generic, or is it the good stuff?" he asks. Upstairs, several teens are sitting at the kitchen table listening to a girl who looks to be about 15 tell how she got the narcotic OxyContin from the medicine cabinet at home. "It was left over" she says, "from my sister's wisdom-teeth surgery".
>
> This isn't an ordinary party – it's a pharming party, a get-together arranged while parents are out so the kids can barter for their favorite prescription drugs. Pharming parties' – or just "pharming" (from pharmaceuticals) – represent a growing trend among teenage drug abusers...Pain medications, which are also powerful nervous-system depressants, are particularly dangerous – and especially prized. "If I have something good, like OxyContin, it might be worth

> two or three Xanax" says a 17-year-old pharming veteran who was one of more than a dozen guests (and one of the few girls) at the New Jersey party. "We rejoice when someone has a medical thing, like, gets their wisdom teeth out or has back pain, because we know we'll get pills. Last year I had gum surgery, and I thought, Well, at least I'll get painkillers" (Banta 2005, p.35).

However, other media sources have cast doubt on the reports questioning the extent, or existence, of the phenomenon. Online United States media critic Jack Shafer, on his website 'Slate', did an extensive piece on the media coverage. This is summarised below from the 'Join Together' site:

> Media reports about parties where youths throw various prescription pills into a bowl at parties first surfaced in 2002, and were echoed in 2003 in a newsletter from the federal Center for Substance Abuse Prevention. More recently, USA Today reported that addiction counselors are "beginning to hear about similar pill-popping parties, which are part of a rapidly developing underground culture that surrounds the rising abuse of prescription drugs by teens and young adults".
>
> But Shafer said the original story quoted no teens or other witnesses to these alleged parties, and said most subsequent stories either relied on anecdotes or were based on earlier reports. National Center on Addiction and Substance Abuse (CASA) chairman Joseph A. Califano Jr. also referenced pharming parties in 2005, when he released a report called, "Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.". But Shafer said that CASA officials told him that Califano was not citing any research.
>
> "CASA does not have quantitative data on the subject of pharming parties; however, we know that the trend exists based on focus groups we have conducted with teens and young adults for various CASA reports where we talk with them about prescription drugs at parties and this is the basis of Mr. Califano's quote", said CASA spokesperson Lauren Duran (Join Together 2006, accessed 21 July 2006).

At this stage, it is probably too early to say whether 'pharming parties' are a 'real' cultural phenomenon among young people or, at least partly, a case of media embellishment. An anecdotal look on a popular online drug user forum, frequented by Australian drug users, only found reference to the United States media stories. Nonetheless, American cultural trends and practices, particularly among youth, eventually seem to be adopted, to greater or lesser degrees, in this country. Further research or investigation into the phenomenon of 'pharming parties' may be required if there is growing evidence of their existence and popularity in Australia.

Patterns of use among recent Victorian injecting drug users (IDUs)

Although limited, one of the best sources of data on patterns of use of benzodiazepines and pharmaceutical opioids by IDUs in Australia is the IDRS. Although the IDRS is limited in this regard, as noted in Chapter 3, as its surveys

of users are limited to quantitative data, some qualitative accounts are provided in interviews with key informants. (See Chapter 3 of this Interim Report for prevalence of use data in Australia and Victoria.)

Benzodiazepines

With regards to patterns of benzodiazepine use in Victoria, Jenkinson and O'Keefe (2006) found that the majority of key informants in 2005 noted a reduction in the injection of these drugs, with most use being oral. While many informants believed that users were increasingly aware of the dangers of injecting benzodiazepines as a consequence of the substantial education programme, they believed that between 10 and 50 per cent of the IDUs they had contact with were still using them intravenously. Key informants believed IDUs were using benzodiazepines to facilitate their abstinence from heroin, while others used them to 'economise' by substituting heroin with benzodiazepines to reduce their heroin intake. A number noted a continuing healthy 'street' trade and observed that clients continued to 'doctor-shop' to obtain benzodiazepines (Jenkinson & O'Keefe 2006, p.57). No data on the street price of benzodiazepines was reported.

Methadone

According to the four respondents in the 2005 Victorian IDRS who could comment, 1ml of methadone solution sold for $1 on the illicit market, a long standing price around the country. One respondent said they exchanged 10 benzodiazepine tablets for 40ml of methadone solution in the previous six months. Two respondents said they obtained their illicit methadone from 'friends'. The IDU suggested prices of illicit methadone had been stable with three of four respondents saying it was 'difficult' to obtain.

Buprenorphine

Of the sample of 150 IDU respondents, 79 per cent had swallowed buprenorphine ever and 53 per cent had done so recently (in the last 6 months). Among those (26%) who injected their prescribed buprenorphine in the previous six months, this was typically done on 26 days in that period, a substantial decrease from 150 days in the previous year's sample). Those (25%) who reported injecting someone else's buprenorphine in the previous six months mostly did this on 10 days over this period, up from six the previous year. In 2005, nine key experts stated that they had experience with clients using buprenorphine illicitly, with one reporting it was their clients' primary drug of choice.

Jenkinson and O'Keefe commented that:

> ...the illicit use of buprenorphine was particularly commented on in the Frankston area, with two key experts drawn from the area indicating that buprenorphine had become a primary drug of choice. In 2004, key experts in that area had reported that buprenorphine was replacing heroin in social

> terms...instead of a heroin market it has become a bupe market and this appears to have been sustained in 2005. In contrast, many other key experts reported that only a small percentage of clients were injecting buprenorphine in other locales throughout Melbourne. There was not seen to be a market for diverted buprenorphine per se, rather 'people injecting their own diverted bupe' (Jenkinson & O'Keefe 2006, p.51).

Morphine

Most of the 2005 IDRS sample preferred injection of morphine to the oral route, with 75 per cent reporting lifetime injection and 39 per cent reporting injecting it in the last six months. Frequency of use and injection of morphine had remained stable since the 2003 IDRS at five days in the last 180. Fifteen per cent of the 2005 IDRS sample (n=23) were able to comment on the price and availability of illicit morphine. Respondents reported that 100mg of morphine costs $50 (range $20–$50); 100mg of illicit MS Contin® had been purchased for $35–50 in the past six months, and 60mg for $20–30. Fifty milligram of illicit Kapanol® had been purchased for between $20 and $50 with 20mg costing between $10 and $50 in that time. Most (65%) reported that the price had been stable in the past six months. Forty-eight per cent believed illicit morphine was 'difficult' to obtain, with the same percentage believing it was 'easy' to 'very easy' to obtain. Most obtained their illicit morphine from friends (65%) or a dealer's home (24%) (Jenkinson & O'Keefe 2006).

Oxycodone

As noted in Chapter 3, in the 2005 IDRS, questions were asked about oxycodone for the first time. Some 17 per cent reported oxycodone use in the last six months with frequency of use appearing very low, typically being four days (out of 180) reported. OxyContin® was the main brand of oxycodone used in that period (Jenkinson & O'Keefe 2006).

Summary

While there is a comparative dearth of in-depth qualitative studies of non-medical users of pharmaceutical drugs, the literature reviewed above along with the submissions and other evidence provided to this Inquiry provides a sense of the reasons these drugs are used. They included: dependence occurring as a result of medical treatment (iatrogenic dependence); self medication; dealing with withdrawal symptoms; drug substitution, enhancement of other drug use; use by clients in opiate treatment; use as a currency by street users; and having a preference for pharmaceutical over street drugs.

The increasing media reports in the United States regarding 'pharming parties' by young people raise an issue that should be followed with interest. While there is reasonable evidence that non-medical use of pharmaceuticals by adolescents in that country has grown, it is unclear at this stage whether 'pharming parties' are a true cultural manifestation of this or largely a media phenomenon. If the latter, there is always a danger that incorrect media

reporting that a phenomenon is widespread may inadvertently lead to the behaviour being seen by young people as 'normalised' and therefore something they should be doing.

Data from the IDRS indicates that while there have been changes in the way drugs such as benzodiazepines have been used, due to such things as the 'heroin drought' and the restrictions on the availability of temazepam in gel form, Victorian injectors continue to use benzodiazepines to deal with withdrawal or economise on their heroin use as injectors have done for many years. Changes in the treatments available for opioid dependence have a flow-on effect on the availability of the drugs in the illicit market, as does the availability of drugs used to treat pain. As acknowledged by Jenkinson and O'Keefe (2006), the increase in non-medical use of pharmaceuticals in Victoria, as elsewhere, necessitates better research to guide prevention, policy and treatment responses.

Acquisition of benzodiazepines and other pharmaceuticals

This section provides some examples of the different ways people attempt to access pharmaceutical drugs such as benzodiazepines and narcotic analgesics for non-medical use. In general it is difficult to know the relative importance of each of these methods in Australia or in Victoria, however there has been some research internationally which has tried to quantify this.

One example is the recent study of illicit opioid users in five Canadian cities (Haydon et al. 2005) which found differences in the source of different prescription drugs used by this group. This is shown in Table 5.1. Thus, benzodiazepines were most likely to be sourced from a friend (46.0%) or a doctor (31.9%), while OxyContin® was equally as likely to be sourced from a regular dealer (45.0%) or a friend (45.0%), followed by a doctor (40.0%). Other opioid medications were more likely to come from a friend (53.0%) or a regular dealer (42.5%).

Table 5.1: Source of selected prescription drugs among illicit opioid users recruited in five Canadian cities

Drug	Regular Dealer % (count)	Irregular dealer % (count)	Doctor % (count)	Partner % (count)	Friend % (count)	Theft % (count)
Talwin & Ritalin	50.0 (21)	4.8 (2)	0	7.1 (3)	47.6 (20)	0
Benzodiazepines	8.8 (2.3)	16.5 (43)	27.6 (72)	3.5 (9)	46.0 (120)	0.4 (1)
Tylenol 3 or 4	12.5 (29)	15.5 (36)	31.9 (74)	3.5 (8)	36.9 (86)	0.4 (1)
Demerol	17.7 (6)	11.8 (4)	32.4 (11)	5.9 (2)	26.5 (9)	5.9 (2)
Dilaudid	37.3 (88)	14.0 (33)	8.1 (19)	3.8 (9)	42.0 (99)	0.9 (2)
Percocet/Percodan	40.9 (45)	19.1 (21)	36.4 (40)	4.5 (5)	56.4 (62)	1.8 (2)
OxyContin	45.0 (9)	20.0 (4)	40.0 (8)	15.0 (3)	45.0 (9)	0
Other opioid prescriptions*	42.5 (85)	20.5 (41)	26.0 (52)	5.0 (10)	53.0 (106)	1.5 (3)

Notes: * e.g. morphine, codeine other than Tylenol 3 or 4, etc.
Percentages can add up to more than 100%, indicating multiple sources of drug access.
Source: Haydon et al. 2005, p.460.

Doctor shopping

> [How many doctors did I go to?] Gosh! Four a day at least. It was like I had a full-time job – 24 hours a day, seven days a week of going through the Yellow Pages. I lived out at [Eastern Suburbs] at the time and I would go as far as [Northern and Southern Suburbs]. I spread out as far as I could go and then I would repeat some sort of format to go back to those doctors and around again and again. Sometimes they would question me, and that is when you become very fearful. Once you have been caught out, it becomes terrifying: (a) you are not going to get the medication and (b) it is very confronting.[115]

Doctor shopping involves patients attending several doctors in order to obtain several prescriptions for controlled drugs in order to obtain a quantity of drugs greater than their therapeutic needs, which are then used for personal consumption or sold on the street market (CASA 2005; Pradel et al. 2004). This phenomenon is not limited to patients seeking drugs from general practitioners, as patients also attend accident and emergency departments of hospitals seeking drugs (McNabb et al. 2006).

Termed 'multiple scripting' by Fountain et al. (1998) in their qualitative study of London drug users in treatment, one of their respondents was asked what was the most prescriptions they had ever held at one time:

> From four doctors: two private, one GP that I was getting methadone from, and one ordinary GP, and that was for Valium and temazepam. The rest was all sorta Class A drugs. But that's a lot for one person – getting four pretty big scripts – it's a lot. You think of every addict that could do that – that's a lot of drugs (Fountain et al. 1998, p.161).

In Australia in 1997 the Health Insurance Commission (HIC), now Medicare Australia, instituted the Doctor Shopping Program in order to: (i) reduce the level of pharmaceutical misuse and thus improve the health outcomes of doctor shoppers; (ii) reduce unnecessary and inappropriate medical appointments and prescriptions; and (iii) refer matters for investigation where criminal activity is involved (Australian Centre for Policing Research 2002, p.9).

In his evidence to this Inquiry Dr Malcolm Dobbin of the Victorian Drugs and Poisons Unit (DPU) explained the criteria for classifying doctor shoppers and his analysis which provides more detail on the scale of the problem:

> They defined doctor shoppers as those people who saw 15 or more GPs in a year, had 30 or more Medicare consultations and appeared to obtain more PBS

115 'Mary', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 20 June 2006. The name and residential location of the person who gave evidence have been changed to protect her anonymity.

> drugs than clinically necessary. I took their figures and calculated the number of doctor shoppers per thousand general practitioners.[116]

Turning Point Alcohol and Drug Centre stated, however, that such a definition is problematic:

> [b]ecause [the definition of] 'doctor-shoppers' excludes people who attend fewer than 15 doctors or fewer than 30 Medicare consultations, attendances of those who use a false identity or Medicare card, or obtain private prescriptions (non-PBS or RPBS subsidised)….Consequently these figures may under-estimate the true prevalence of acquisition of these drugs for non-medical purposes.[117]

As such, the true number of doctor shoppers operating in Australia may have been seriously underestimated.

In 1997, Australia-wide, there were 1,270 doctor shoppers per 1,000 GPs and in Victoria there were 1,447 per 1,000. Prescriptions filled by doctor shoppers nationally included 59 per cent for psychotropic drugs of misuse including benzodiazepines (35%), codeine compounds (15%) and narcotic analgesics, with the remainder being medicines for other conditions, many of which appeared to be obtained on the PBS and then taken overseas for relatives or for sale.[118]

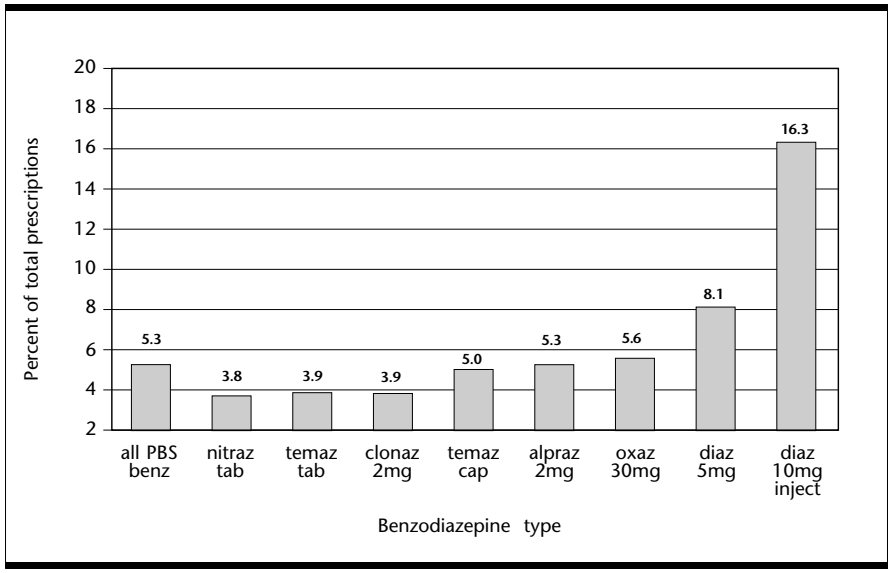
Dr. Malcolm Dobbin found that the prescriptions for benzodiazepines dispensed under the PBS, which had been obtained by the doctor shoppers identified under the HIC's programme, was considerable (see Figure 5.1.).

116 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

117 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and Other Pharmaceutical Drugs in Victoria, May 2006.

118 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

Figure 5.1: Per cent of total PBS benzodiazepine prescriptions obtained by 'doctor shoppers' in Australia, 2000



Notes: all PBS benz = all benzodiazepines available on the Pharmaceutical Benefits Scheme
nitraz tab = nitrazepam tablets
temaz tab = temazepam tablets
clonaz = clonazepam
temaz cap = temazepam capsules
alpraz = alprazalam
oxaz = oxazepam
diaz = diazepam

Source: Extracted from presentation made by Dr Malcolm Dobbin to the Dugs and Crime Prevention Committee, Briefing, 29 May 2006.

Dr Malcolm Dobbin remarked to the Committee:

> It is alarming. I was totally alarmed, but then when I looked at the figures for opioids I was even more alarmed. I find it astounding that this proportion of PBS drugs could be obtained by this small group of drug-seeking patients.[119]

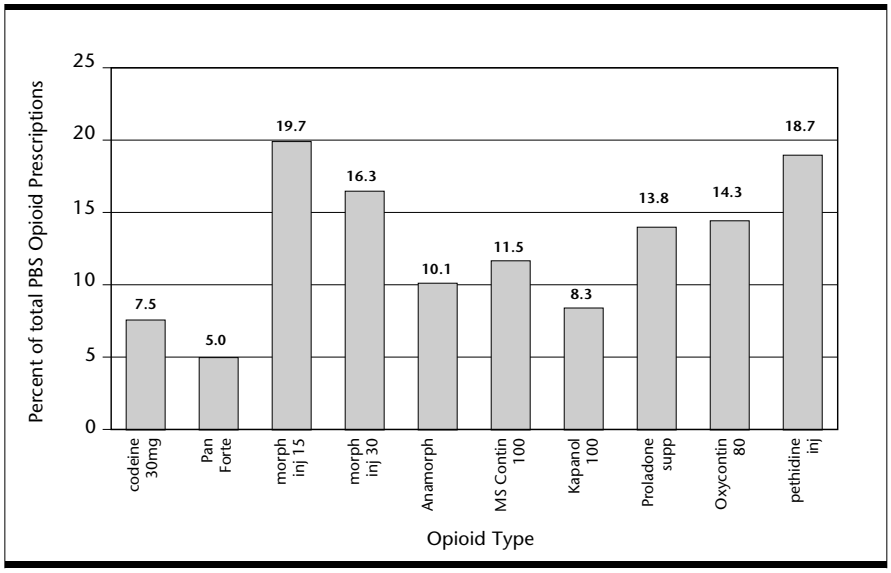
Referring to the data provided in Figure 5.2 below he noted:

> You can see the morphine injections here and here, and pethidine injections, one in five or one in seven, but then the high-dose 100-milligram Ms Contin – that is, 100 milligrams of morphine – or the OxyContin 80-milligram, which is another high-dose formulation. But probably the biggest number would be the Panadeine Forte or similar products, containing 30 milligrams of codeine as well. This is a big-volume item. This probably accounts for the biggest number of diverted scripts.[120]

119 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

120 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

Figure 5.2: Per cent of total PBS opioid prescriptions obtained by 'doctor shoppers' in Australia, 2000



Source: Extracted from presentation made by Dr Malcolm Dobbin to the Dugs and Crime Prevention Committee, Briefing, 29 May 2006.

Thus the Australian data indicate that doctor shoppers account for significant proportions of all the prescriptions filled on the PBS for benzodiazepines and narcotic analgesics, including almost one in five prescriptions filled for injectable formulations of morphine and pethidine.

One of the problems with the Doctor Shopping Program is that it only captures prescriptions within the PBS. However, other prescriptions are prescribed through private prescribers where the scripts are not registered with the PBS. One group of patients who are often prescribed large amounts of benzodiazepines or narcotic analgesics are victims of motor vehicle accidents, whose accident claims are managed by the Transport Accident Commission (TAC). Evidence provided to the Inquiry by the TAC suggested that significant proportions of their clients were not on PBS scripts and were not being identified by the Doctor Shopping Program. As an example, with regards to narcotics it was explained:

> We ran a project which looked at schedule 8s, those substances which you would think were of significant risk. It comprised 10 percent of the items that we were receiving, so roughly 100,000 items a year. On scanning, 20 percent looked like the way they were being managed was unusual and needed review; probably had some significant clinical issues. When you are looking at an account you are talking about doses and quantities. Of that 20 percent, we made the effort to trawl those and work on them one by one. Forty-one percent of [that group] had pre-existing, pre-motor vehicle accident drug related issues, either drugs of addiction issues, illicit substances, or substance abuse of a prescribed nature. Fifty-four percent of the doctors were prescribing non-PBS,

> meaning private scripts, which meant that it was outside a regulated process of review, so it was going to [be] miss[ed by] doctor shopping and pharmacy shopping [programmes].
>
> Fifty-one percent of the doctors prescribed without a permit. The normal permit system that the drugs and poisons unit has in place is that you need a permit after a certain period of time using a particular substance, or immediately, with certain substances which are very high risk. Roughly half the doctors were not following the law. There was a significant problem with the misuse of injectable narcotics. We are talking about morphine and pethidine. There were very high quantities and circumstances where you would not normally use those substances. We do not have the capacity to assess the extent of diversion. Here we are talking about individuals who are getting high quantities of schedule 8s. The extent of diversion we assume, we do not know.[121]

Martyres, Clode and Burns (2004) conducted an analysis of Victorian Coroners Court records linked with PBS data relating to the death of 254 persons aged 15 to 24 from heroin-related overdose between 1994 and 1999. The data showed that, in the years before they died, their doctor shopping escalated with an increase in both the number of doctors seen and rates of prescriptions issued. Their doctor shopping peaked in the year before they died. The researchers found that although all prescriptions increased before death, those for opioids and benzodiazepines increased more than other drugs. They concluded that while doctor shopping is primarily viewed as an economic problem, they believe that further research into escalating drug seeking behaviour by young heroin users may provide a clinical predictor of overdose risk and an opportunity for intervention and preventing overdose fatalities (Martyres, Clode & Burns 2004).

The Victorian YSAS also believes that doctor shopping has to be viewed as other than just an economic or even drug seeking problem. In evidence to the Committee, Tony Palmer from YSAS queried whether doctor shopping, at least in some cases, might not be viewed as a 'cry for help' from young people in crisis. He asks:

> [w]hether what is normally called 'doctor shopping' is actually doctor shopping or whether it is a form of help seeking, because we have seen this link between doctor shopping and suicide. The question is whether, at a point where the young person is getting really agitated and really anxious about life, they then start doctor shopping in the hope that somebody can offer some kind of answer to what is going on.[122]

121 Dr Peter Harcourt, Chief Health Officer Health and Disability Strategy Programmes, Transport Accident Commission, 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 Hearing, Melbourne, 19 June 2006.

122 Mr Tony Palmer, Trainer and Consultant, Youth Substance Abuse Service, 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 Hearing, Melbourne, 20 June 2006.

Certainly this is an issue that requires further exploration in ongoing work pertaining to this Inquiry.

One of the consequences of doctor shopping is that it increases the amounts of pharmaceutical drugs that are available on the street illicitly, which poses problems for those clinicians servicing that population. This is explained by Dr Frei:

> This is how drug markets have changed in the last five years, I think. Ten years ago, if somebody said that they were on Valium or one of these benzodiazepine drugs, they would be getting them from a doctor and you would be able to confirm it with the doctor. Now there seems to be this huge street availability of these drugs. They are traded on the street and it is really difficult. Ten years ago we could have rung the doctor and the doctor would have said, 'Yes, I prescribed this person. It's a bit too much, but this is what they get', and they may not have been doctor shopping. Nowadays, they might be going to half a dozen doctors, getting them from friends or buying them from people on the street. That group is really difficult to work out. With this huge reservoir of illicit drugs being traded on the street, it is very hard to get an idea of how much somebody is using. Because a lot of these drugs cause a bit of amnesia, they might forget how much they have used. That is one of the big difficulties. In fact, with heroin I have always found the illicit drug users easy. They say, 'This is how much heroin I use. I buy it each day', and, strangely, it is a bit easier to deal with. The licit drug users who are haphazardly buying prescription drugs on the street are really quite tricky.[123]

Methods used by doctor shoppers

It would seem that the methods used by doctor shoppers to seek and access prescription drugs illegitimately are many and varied. This was certainly the case in one study by Fountain et al. (1998). The authors presented results from their qualitative study of drug users in treatment to demonstrate the strategies drug users employed to obtain surplus drugs to sell on the illicit market. A selection of them is presented here.

Overscripting – Here the client gets prescriptions for larger amounts of a drug than they need for themselves. Fountain et al. (1998) give the example of 'Maurice':

> I always keep my own juice (methadone mixture) – well, I sell a bit of it occasionally, but I need most of it myself, or I'd be sick (withdraw)…I do sell pills (benzodiazepines) when I get them for myself…I mean, when I get my temazi (temazepam) and Valium script, I just take a couple – like a couple with a hit (injection of heroin) or a couple to go to sleep with…I get 60 of each a month, and, like, on average, I take out of them half a dozen (Fountain et al. 1998, p.161).

123 Dr Mathew Frei, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

Exaggerating their dependency – The most frequently used strategy was for users to exaggerate the amount they used themselves. The authors note that this often put the doctor in a difficult position where benzodiazepines were concerned, because if the story of excessive use was true, abrupt cessation could precipitate a seizure.

> Sally: I had no pill addiction whatsoever, but I went in there with a sob-story saying 'I'm using ten Mogadon, eight blue Valium (10 mg) a day, and buying them off the black market, and I have to thieve to get the money, and I don't want to do that any more, and I want to try and sort out my life' and so forth, and what she said was 'Out of the two drugs you're taking, I can only prescribe one of them'. So I said to myself 'Right, Mogadon is 5 mg, Valium is 10 mg – so I'll have the Valium'. And when it came to the amount, I said I was using 12 blues (10 mg Valium tablets) a day, which is 120 mg a day…it's a hell of a lot, but I said 'I've managed to cut myself down to 80 mg' and she said 'Oh, brilliant'. So therefore, I get 56 blues of 10 mg a week, and I pick them up fortnightly, which is 112 blue tablets, take a couple myself, and the rest I sell (Fountain et al. 1998, p.162).

A submission to this Inquiry by a former self-termed 'addict' of prescription drugs also testified to how she would on occasion overstate the pain being suffered for her (legitimate) illness in order to obtain the drugs she craved. As she succinctly put it: 'One of the first "skills" to master when doctor-shopping is acting – and desperation for a drug is an extremely good teacher'.[124]

Bargaining with prescribers – This involved what one might call 'emotional blackmail' to say that, unless they were prescribed the pharmaceuticals, they would have to engage in sex work, or commit other crimes, in order to buy heroin to feed their habit. Where a prescriber suggested decreasing the client's dose this could be met with a threat to top up their dose by using extra from the illicit market (Fountain, Griffiths, Farrell et al. 1998, p.162).

Gaining sympathy – As indicated above, women spoke of using 'sob-stories' to get the drugs they wanted, or presenting a hopeful story of real effort towards change.

> Lucy: You tell them what you know they want to hear...God forbid, my mother, she has died more times…she's had car accidents, she's died of cancer, and I've been grieving, 'I've got to go the funeral, I need this and this and this', and it's amazing how quick those tears dry up when you see that pen writing the script.
>
> Sally: Basically, she's of the understanding that I'm going to get myself into a treatment centre, so therefore she's more accommodating...I do sort of feed her positive information, like I am sticking to my script, like my mum gives them to me on a daily basis, so there's no chance of me abusing them…So when I go there, and I have a little chat with her – some of it's a load of bullshit

124 Submission to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, April 2006. The name of the author of this submission has been withheld to protect her anonymity.

> obviously, and some of it's the truth – and she thinks maybe I am trying…(Fountain et al. 1998, p.163).

Feigning addiction – Fountain et al. (1998) also found several clients who obtained benzodiazepines from a general practitioner by claiming addiction to alcohol rather than opiates.

Claiming to be a temporary resident – Presenting oneself as a visitor from out of town who has run out of medication was another strategy that worked well for clients seeking extra pharmaceuticals.

> I've actually been guilty of going into a doctor's out of the blue and he has just gone 'bosh' (written out a prescription)…yeah, as a temporary resident, say from the North, and I've walked out with temazepam, diazepam, and DFs (DF118). That's on the first visit…Then you walk round the corner and do it again, and you've got your pockets full and you've earned yourself a few bob – you sell them and you've got the money to buy your own stuff (preferred drugs) (Fountain et al. 1998, p.164).

Mr Steve Marty, the Registrar of the Victorian Pharmacy Board, related to the Committee how ingenious some doctor shoppers could be in this regard:

> We have had occasions where a deregistered nurse photocopied a prescription for Ritalin. It was an extremely good photocopier because it looked like the writing had been with a felt-tipped pen. But she managed to present these to a substantial number of pharmacies, none of whom picked up that it did not have the quantity in words, which is one of the requirements at the moment and should have raised suspicion. Once again, people who do this use all sorts of measures to lower suspicion thresholds of pharmacists. This woman was always immaculately dressed. She would go in and say, 'Can I leave my prescriptions here with you and I'll get them when I need them?' She would go in the next day or the day after when a different pharmacist was on duty and say, 'You've got my prescriptions here', so there was some assumption that she was a regular customer.
>
> She got a lot of these prescriptions and she would go in a few days later and say, 'I'm running a sales conference in Sydney. I'm not allowed to get these dispensed up there. Could I take my repeat so I'll have enough to last me whilst I'm away?' Very clever ruses that, if people present well, might easily be accepted. She was detected because she went to a pharmacy across the other side of town but the pharmacist on duty that day had been on duty in the eastern suburbs where she had presented the day before, so she was picked up as a result of that.[125]

A similar case was described by Dr Malcolm Dobbin in his briefing to the Inquiry:

125 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, 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 Hearing, 19 June 2006.

> One man we have heard of is in his 40s. He has had a coronary artery bypass graft, so he has a midline sternal scar through here. He presents to the doctor and says, 'I've just moved from interstate' or 'from the country. Will you be my doctor?' He spends 20 minutes or half an hour going through what he needs, and the doctor examines him. It all looks pretty genuine. He is getting his heart tablets, his cholesterol tablets, his hypertension tablets, and as the doctor is writing the script he says, 'Oh, by the way, can you put a script on there for temazepam capsules'…He has disarmed the doctor. I have a lot of sympathy with the doctors.[126]

A 'successful strategy'

One of the respondents in the London study thought that persistence usually paid off when scamming doctors: 'Just take pot luck, because at the end of the day, the doctor can only say no. The chances are you are going to get something off someone' (Fountain, et al. 1998, p.164). Another, who had a 20-year history of doctor shopping, explained the enjoyment she had from outwitting the prescribers:

> I used to enjoy doing it. I believed what I was saying. I never ever got nicked…You're always scared, but sometimes that's part of the fun of it. Especially if you know someone that's already hit that doctor and you think that you can get a lot better than them and you do it; it's quite a buzz. I mean, I always felt so clever when I came out: I'd pulled it off perfectly and thought, 'What a liar I am: that poor doctor is totally taken in by this. They're trying to help me – there's nothing wrong with me, I've just gone in with this load of lies and he's believed this'. And what you have to do – the trick to it is that you have to believe it yourself when you go in that room, go through that door. You believe what you say and you're so convincing 'cos you believe every word you're saying. If you didn't do that, you know, if you faltered at all, you wouldn't get it. You've got to be convinced that it's true and that doctor will believe you. Nine out of ten will believe you (Fountain et al.1998, p.165).

Reflecting on his experience of talking about the doctor shopping issue to Australian doctors, Dr Malcolm Dobbin stated:

> I must say it is hard for the individual doctor. Some people are very clever and present plausibly; others are evident and you are immediately put on your guard...I have presented this kind of thing in educational addresses to doctors, and one doctor came up to me afterwards and said, 'I work opposite the flats and I always have people coming in and saying, "Look, I've just moved from interstate and I need my blood pressure medication" or "my heart pills" or "my water pills", and there are occasions when they come in and say, "I need my heart pills and

126 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

> my Serepax", and they look just the same as all my other patients. They've got morbidity, they have scars. I genuinely can't tell the difference'.[127]

Steve Marty, Registrar with the Pharmacy Board of Victoria also expressed his sympathy for the difficult situation of most doctors, when he gave evidence to this Inquiry:

> When many medical practitioners prescribe, of course, they are relying on a truthful history being presented by the patient and, to a certain degree, you have to accept it unless you want to be in an argument or accuse the person of lying or interrogate them further. So they do need to have very good diagnostic skills, but these people also are very skilled in the way that they present information: they will have done their research, know what to say; they will know all of the symptoms sometimes better than some of the practitioners involved, I suspect. Once again, there is no central history that you could look up. GPs come under pressure, certainly from aggressive behaviour, threats to them or to patients waiting in the reception area. There have been occasions where friends have caused substantial trouble in the waiting areas and all the GP wants to do is get them out of the surgery, so [the GP] will write a prescription.[128]

Forged, stolen or altered prescriptions

Evidence has been given to this Inquiry from several sources testifying to the relative ease with which people can forge, alter or otherwise illegally obtain prescriptions or prescription pads.[129]

For example, a submission from the Pharmacy Board of Victoria to this Inquiry explained that:

> Benzodiazepines have commonly appeared on forged or altered prescriptions and have been the target of pharmacy break-ins.
>
> Forgeries can be on both handwritten prescriptions and more recently computer generated prescriptions. Similarly, alterations have been made to handwritten prescriptions, usually by increasing the quantity originally ordered by the prescriber and/or the number of repeats to be supplied.
>
> Computer software for prescribing has been fraudulently obtained on occasion and used to generate unauthorised prescriptions and also cases where scanners using optical character recognition programs to copy a genuine computer

127 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

128 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, 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 Hearing, Melbourne, 19 June 2006.

129 Forgery of prescriptions for both drugs of dependence and other forms of drugs and medicines are punishable by fines and/or imprisonment. See provisions of the *Drugs, Poisons and Controlled Substances Act 1981* discussed in Chapter 6 of this Interim Report.

> generated prescription and then change patient details, drug, quantity and number of repeats have resulted in fraudulent supply of drugs.[130]

The Victorian Forged Prescription Study (Lloyd, Guibert & Bell 2000) conducted for the Victorian Branch of the Pharmaceutical Society of Australia Ltd. was an attempt to address the issues related to forgery of prescriptions and to assess the nature and extent of forgery in the Victorian community. The project included literature reviews and interviews and surveys of key stakeholders. Their survey of 772 pharmacists in Victoria found that roughly equal proportions believed forgeries to occur rarely (40%) or frequently (39%). Perception of frequent prescription forgery was greater in suburban Melbourne (46%) than in rural Victoria (18%), and was also greater among those with more years of practice (Lloyd, Guibert & Bell 2000).

In addition to making a number of recommendations as to how the problem could be addressed, Lloyd, Guibert & Bell (2000) analysed data from the Department of Human Services (DHS) database of forged prescriptions for the period January 1997 to March 1999. The DHS expects doctors to advise it if they become aware of their prescription stationery being stolen or used for forging prescriptions. At that time they found a fairly stable rate of forgeries reported, with a slight tendency for the forgeries to be on stolen stationery, rather than adulteration of bona fide prescriptions (see Table 5.2). The authors concluded that:

> A significant number of both doctor and pharmacy practitioner groups demonstrated that they are generally not aware of the true extent of the problem of forgery, nor of their individual legal and professional responsibilities (Lloyd, Guibert & Bell 2000, p.ix).

Table 5.2: Distribution of prescription forgeries reported to the DHS Drugs and Poisons Unit from 1 Jan 97 to 15 March 1999

Year	Number of names used by forgers	Numbers of forgeries		Number of different drugs sought	Number of pharmacies at which prescriptions were uttered	Number of different doctor's stationery used	Number of doctors reporting stationery stolen
		Alterations to genuine prescription	Forged on stolen stationery				
1997	146	73	99	191	155	90	33
1998	121	76	51	124	112	49	25
1999 *(until 15Mar)*	41	15	28	38	38	27	8

Source: Lloyd, Guibert & Bell 2000, p.19.

Consistent with the above data, Forgione, Neuenschwander and Vermeer (2001) noted that most of the prescription forgery in the United States involved stolen, or printing of phoney, prescription pads.

> The primary source of prescription forgery is the forgery of prescription pads. Prescription pads can easily be printed with phony names, addresses, telephone

130 Submission of the 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 2006.

> numbers, and DEA [Drug Enforcement Agency] numbers. Some scammers travel around the country breaking into physicians' offices or even setting up their own offices. Others may include a cellular phone number on the prescription pad – the pharmacist then reaches an accomplice who poses as the prescribing doctor and confirms the prescription over the phone, thus relieving any concerns the pharmacist may have (Forgione, Neuenschwander & Vermeer 2001, p.66).

In his briefing to the Inquiry Dr Malcolm Dobbin described one case of doctor shopping in Victoria involving stolen prescription pads used to facilitate temazepam diversion:

> We have pharmacists and other inspectors who go to pharmacies and trawl through the pharmacists' records case by case, and in this case they have identified a number of forged prescriptions obtained by this particular man and woman team. The inspector identified 300 prescriptions over three months made out to this particular person and did not have any way of knowing whether there had been others forged under other names. They had been obtained from 77 different pharmacies and they were mostly done on prescription pads that had been obtained by breaking into a doctor's surgery, but they had also been taken from a doctor's desktop when the doctor was distracted. So you can see the difficulty, using our current methods, in trying to detect and prevent the dispensing of these drugs. These had been dispensed. At that time temazepam capsules were being trafficked for $50 a prescription – a slab, as it is called, of capsules – or between $10 and $20 a capsule.[131]

In the United States it has been observed that some people seeking pharmaceutical drugs have had their own prescription pads printed at commercial print shops, as this doesn't require special credentials (Blumenschein 1997). Yet, even if there are checks to guard against this practice, with cheap and widely available high quality colour scanners, printers, photocopiers and desktop publishing software, legitimate prescriptions can also be copied, producing very professional looking fakes.

Prescription forgery scams can be very sophisticated and hard to detect, as demonstrated by the following two notorious scams in America:

> In these situations, prescription pads are printed utilizing a fictitious physician name, practice address, DEA number, state license number and phone number. When a pharmacist tries to verify the prescription by contacting the prescriber using the phone number listed on the prescription, the forger's accomplice will pick up on the other end and pretend to be the physician. In some cases the phone number listed on the prescription goes to a hired answering service that forwards the message to the phony physician who calls the pharmacist back to "verify" the prescription. Criminals using this kind of scam diverted over 60,000

131 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

> dosage units of Dilaudid from 1990–1993 in Florida (Blumenschein 1997, p.186).
>
> Prescription drug scammers have also called a physician's office, found that it was closed, and then called the physician's answering service impersonating the physician and asking to have all the physician's calls held. The individual then dropped the prescriptions for controlled substances at numerous pharmacies. After a few hours, the scammer would call the physician's answering service to check for messages. If a pharmacy did not call, the prescriptions would be picked up at that pharmacy (Forgione, Neuenschwander & Vermeer 2001, p.66).

Blumenschein (1997) concluded that altering prescriptions can be one of the easiest methods of prescription fraud. Changing the quantity prescribed or the number of repeats to be dispensed is easier if the prescriber is not careful how they have written it. For example, when quantities are written as numbers and not spelled out they can be more easily altered, or a digit added. Similarly, if the number of repeats is not specified clearly it is a relatively easy task for the forger to adjust the script for the maximum number of refills. Less commonly, a second drug can be added to a legitimate script, or the strength of a preparation can be increased. In Victoria the Drugs, Poisons and Controlled Substances Regulations 2006 do require the quantity of the prescribed medicine and the maximum number of repeats of Schedule 8 and 9 drugs to be written in both words and figures.[132] It is unclear, however, as to why such a stipulation should not also apply to the prescribing of Schedule 4 drugs, which include most benzodiazepines.

Another strategy is when the prescription drug seeker phones the pharmacy posing as a prescriber or nurse, often after hours or on weekends when the pharmacist is least able to contact the prescriber (Blumenschein 1997, pp.186–7).

Lloyd, Guibert & Bell (2000) surveyed some 668 Victorian general practitioners regarding prescription forgery. Among this group 37 per cent perceived the practice as 'frequent', 28 per cent as 'rare' and 35 per cent 'did not know' (p.47). Overall, the authors concluded that forgery probably contributes less to net pharmaceutical drug abuse in Victoria than other methods of acquiring pharmaceuticals illegitimately. However, because it requires little skill compared to other methods (such as misrepresenting themselves to doctors), and the risk of detection is probably low, it is still frequently used (Lloyd, Guibert & Bell 2000).

Acquisition from friends and family

Friends and family constitute a major source of prescription drugs used for non-medical purposes. A submission by the YSAS noted that 'Benzodiazepines are

132 See Regulation 26, Drugs, Poisons and Controlled Substances Regulations 2006.

generally first accessed by raiding a parent's or other relative's legitimate supply'.[133]

A young person cited in a United States study stated:

> I can get prescription drugs from different places and don't ever have to see a doctor...I have friends whose parents are pill addicts, and we 'borrow' from them. Other times I have friends who have ailments who get lots of pills and sell them for cheap. As long as prescription pills are taken right, they're much safer than street drugs (18-year-old male from San Francisco) (Friedman 2006, p.1448).

In a web-based survey, McCabe and Boyd (2005) surveyed 9,161 undergraduate students attending a large public Midwestern research university. The respondents identified 18 sources of prescription drugs for illicit use that were classified into three broad categories: peer, family and other sources. Those who obtained prescription drugs from peer sources reported significantly higher rates of alcohol and other drug use than students who did not use prescription drugs illicitly or who sourced their drugs from their family.

Although admittedly anecdotal, some evidence given by a representative of the Interhospital Group to this Committee suggests there may also be a culture of inter-generational acceptance of the use of prescription drugs. In other words parents, particularly mothers, may pass on their own prescription drugs to members of the family without first considering whether this is appropriate:

> [p]articularly in the western and northern region where it is culturally accepted; it is almost a rite of passage for girls to start their benzo use at about 14, 16, because that is what mum and grandma and everyone had done. They do not come into treatment services because 'Why get off them?'[134]

Just as family members might supply their own drugs to another family member, it is not unheard of for a family member, friend or acquaintance to divert the drugs of the person to whom they are legitimately prescribed, sometimes even after they are dead:

> We have an increasing incidence of cancer hospital in the home, people who want to die at home; so community pharmacies are often called upon to dispense 120 ampoules of morphine. When the person dies, there are occasions where the grandchildren or the son or daughter decide that this might produce some alternative income or they have been stolen from home. There have been instances where patients have been assaulted after leaving pharmacies, often because the pharmacy has not been smart enough to put these into an opaque bag so that people are not aware of what they are getting. If you are in the right

133 Submission of the Youth Substance Abuse Service to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

134 Ms Ros Burnett, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

> environment and somebody sees this, it is worthwhile taking it. That is part of the difficulty.[135]

The non-medical use of pharmaceutical drugs such as narcotic analgesics and benzodiazepines often has a long tradition in small communities far from the major sources of heroin supply. This is the case in the two smallest heroin markets in Australia, the Northern Territory and Tasmania, where diverted pharmaceutical drugs, rather than heroin, have long dominated the illicit drug market. The role of friends and family in supply of these drugs in the Northern Territory has recently been described in an article by Topp that discusses the extent to which non-medical use of pharmaceutical drugs could be less harmful than the use of street drugs.

> We know relatively little about the methods by which pharmaceuticals are diverted to the black market, although Darwin academic Dr Bridie O'Reilly suggests supply is driven mainly by small-scale diversion from legitimate prescriptions, doctor shopping and forged prescriptions, rather than through organised thefts from pharmacies or points of manufacture, or via other sources such as internet pharmacy or importation.
>
> Dr O'Reilly says prescription drugs are relatively easy to obtain from a diffuse network of users, friends of users, dealers and suppliers, some of whom also sell other drugs, such as methamphetamine, heroin and/or cannabis. There is little, if any, involvement of organised criminal groups, and the violence and criminality that typically characterise heroin markets are absent. Dr O'Reilly cites this feature as a significant advantage of a pharmaceutical-dominated market (Topp 2006, p.7).

The role of health care providers in diversion of pharmaceutical drugs

The previous discussion focussed primarily on the role and actions of people who were seeking prescription drugs illegitimately. But health care providers, particularly prescribing doctors, also contribute to the problem either through inattentiveness, incompetence or even questionable ethical behaviour.

In 1980, the American Medical Association adopted a taxonomy termed 'The Four D's'– the dated, the disabled, the dishonest and the duped – to describe doctors who over-prescribed medicine (Forgione, Neuenschwander & Vermeer 2001). This taxonomy seems to provide a useful shorthand way to describe the different reasons that doctors might over-prescribe:

- Dated doctors are those who make their therapeutic decisions based on outdated, incomplete, or incorrect information;
- Disabled physicians are those who misprescribe due to their own mental illness or own addiction problems;
- Dishonest doctors are those who use their medical license to deal drugs for their own financial benefit; and

135 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, 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 Hearing, Melbourne, 19 June 2006.

- Duped doctors are those who unintentionally prescribe drugs to a user based on false information provided by the patient (Forgione, Neuenschwander & Vermeer 2001, pp.66–68).

Some dishonest medical practitioners, termed 'script doctors', prescribe benzodiazepines, narcotics or other misused pharmaceuticals to patients who they know will abuse them, in exchange for money, sexual favours or other forms of recompense. Such doctors are in essence using their medical licence to deal drugs illegally (CASA 2005). Pharmacists or other pharmacy staff can also divert pharmaceutical drugs by forging prescriptions for drugs which they then sell illegally, or using patient and provider information from the pharmacy database to 'create' prescriptions (CASA 2005).

In a recent study of media reports of controlled drug diversion in the United States, Brushwood and Kimberlin (2004) concluded that between 1992 and 2003 media stories on diversion by dispensers increased by 350 per cent. This compared to increases of 200 per cent for prescriber diversion, 133 per cent for pharmacy robbery and thefts, and 1,800 per cent for thefts from supply channels. Media reports on physician and pharmacist diversion included:

- On November 16, 2001, the Dayton Daily News (Ohio) reported that a pharmacist had been charged with drug trafficking, after his employer reported he entered data into a computer for prescriptions that did not exist.
- On September 12, 2002, the Knoxville News Sentinel reported that a Jefferson City, Tenn., pharmacist pled not guilty to charges of illegal distribution of prescription narcotics.
- On September 13, 2002, the Augusta Chronicle (Ga.) reported that a physician had pled guilty to prescribing narcotics without legitimate medical reasons, and the physician faced a maximum sentence of up to 25 years in prison and $1.25 million in fines.
- On October 9, 2002, the Houston Chronicle reported that a local physician had paid a $75,000 fine for prescribing controlled substances for other than a valid medical purpose. The physician had voluntarily surrendered his Drug Enforcement Agency registration (Brushwood & Kimberlin 2004, pp.441–442).

The above discussion relates for the most part to inappropriate behaviours of doctors in their role of prescribing drugs for *other* people. It is not unknown, however, for health care professionals *themselves* to abuse the drugs over which they may have control or access. This is the subject of the next section.

Diversion by health care providers for their own use

There has also been a longstanding recognition that doctors, nurses and pharmacists are at increased risk of using drugs for non-medical purposes, associated with their high levels of access to these drugs. For example, evidence suggests that in the USA between 40 and 65 per cent of pharmacists have used a

drug illicitly at least once during their professional careers and some 20 per cent have done so at a level where they have experienced negative, health, vocational or relationship consequences (Dabney & Hollinger 2002; Hollinger & Dabney 2002). Mr Steve Marty, Registrar of the Pharmacy Board, indicated that the abuse of medical professionals with access to prescription drugs is a cause for concern:

> Self-prescribing and self-administration by health practitioners is prohibited by legislation, and yet we still see this happen often enough. Medical practitioners think, well, why shouldn't they be able to treat themselves? I would suggest that no-one can rationally treat themselves; it is not possible. You see some very skilled people who have serious abuse problems and still continue to practise and put their patients at risk. You really doubt what their mental capacity is for rationalising their own situation.[136]

A submission to the Inquiry from the Nurses Board of Victoria also noted that:

> In the 2004–2005 Nurses Board of Victoria Annual Report, there were a total of 23 complaints that included the misuse/abuse of medications, including the misappropriation of medications from the workplace. However, these complaints must be considered within the context of a lack of a legislative framework that requires mandatory reporting. The Board is aware that not all incidents are reported to the Board, including some situations where the employer chooses to manage the incident within the employment relationship...The drug classes that appear to be the most prevalent in complaints received are narcotics and benzodiazepines.[137]

A recent study of diversion cases involving health care workers in Cincinnati from 1992 to 2002 (Inciardi et al. 2006) found that opioids followed by benzodiazepines were the drugs most often diverted, with nurses (63.4%) responsible for most of the cases, followed by physicians (8.7%), medical assistants (6.4%), pharmacists (6.0%) and nursing assistants (5.0%). Hydrocodone (20.0%) was the most widely diverted drug, followed by oxycodone (immediate release) (15.6%). OxyContin® was only mentioned in 2 per cent of cases, as apparently it was not routinely available through much of the period of the analysis, and because of media scrutiny special care was taken to restrict diversion (Inciardi et al. 2006). Most of the diversions in this study appeared to be for the health care providers' own use.

The legal consequences of such behaviour are discussed in Chapter 6 of this Interim Report.

Retail theft

Benzodiazepines, narcotic opioids and other controlled drugs can be stolen

136 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, 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 Hearing, Melbourne, 19 June 2006.

137 Submission of the Nurses 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 2006.

from pharmacies, doctors' surgeries, dentist practices, veterinary clinics, hospitals, nursing homes and from individual patients. Theft can occur by shoplifting, robbery or burglary (CASA 2005). The Victorian Branch of the Pharmaceutical Society of Australia (Lloyd, Guibert & Bell 2000) considers that while thefts from pharmacies and wholesalers have long been a source of drugs for pharmaceutical drug abuse and will continue to be so, stringent security measures now in place have reduced thefts from these sources.

In his evidence to the Inquiry Dr Malcolm Dobbin noted:

> There is breaking and entering into pharmacies, and during the time that temazepam capsules were favoured for abuse there was a spate of pharmacy thefts. I have heard a pharmacist the subject of a pharmacy break-in describe the observations of one of the shopkeepers across the road. People pulled up in a car and, with a sledgehammer smashed the door down, walked in, went to the pharmacy storage area where the drugs were stored, took all of the temazepam capsules and left the temazepam tablets, on the way out smashed a camera and took a few sunglasses and some perfume, and were gone within five minutes. There was also a series of ram raids where people stole cars, drove through the windows of pharmacies and stole temazepam capsules.[138]

Also referring to pharmacy burglaries during the time when temazepam capsules were available, Mr Steve Marty described how:

> It used to surprise me that, on visiting pharmacies, I would look at the top shelves and say, 'You must have a wish to be broken into, because if you're going to have 12 dozen on display up there, you might as well have a sign at the front door that says, 'After-hours drug supply, break glass and enter', because that is exactly what happened. There were ram raids, where they use a car, back into the front door, smash it and get in and out within a couple of minutes. Those capsules were sold for $5 on the street, so if they stole a couple of hundred bottles of 25, there was a big return for them.[139]

Even though hold-ups of pharmacies for narcotic pharmaceuticals may have decreased in frequency over recent years, they still occur:

> Narcotics, of course, are a source of armed hold-ups to pharmacies. It comes and goes. There was recently one in the Mornington Peninsula where the person demanded specific drugs. They would have done their homework to work out that that pharmacy happened to have a number of people taking Ritalin and oxycodone. They are well informed in this.[140]

138 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

139 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, 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 Hearing, Melbourne, 19 June 2006.

140 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, 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 Hearing, Melbourne, 19 June 2006.

In the United States, concern about theft of drugs from pharmacies is increasing and in recent years OxyContin® has been the goal of the bulk of pharmacy robberies across that country (CASA 2005).

Theft from pharmaceutical companies and wholesalers

The Australian Centre for Policing Research (2002) in their report *The diversion of pharmaceutical drugs onto the illicit drug market* noted that while the value of pharmaceutical drugs creates the possibility of diversion at the wholesale or retail level, the degree of monitoring that occurs over all levels of the supply chain for Schedule 8 drugs (but not for lower scheduled drugs) meant it was less likely that large-scale diversion from the supply chain would occur. The Victorian Branch of the Pharmaceutical Society of Australia shares this view (Lloyd, Guibert & Bell 2000).

In the United States, CASA (2005) has indicated that there are a number of opportunities in the supply chain for diversion to occur. Drugs may be stolen from wholesalers and sometimes exchanged for counterfeit drugs. Drugs can change hands several times along the supply chain before reaching the end user. Further, the 1,800 per cent increase in media stories on wholesale supply theft in the United States noted above (Brushwood & Kimberlin 2004) indicates a substantial problem in that country, if not in our own.

Access by those engaging in criminal or other activity

Some patients engage in organised criminal schemes to acquire pharmaceutical drugs to re-sell on the illicit market. For example, Forgione, Neuenschwander and Vermeer described a scheme in Chicago which:

> employed 'professional' cancer patients. When doctors were confronted with a quadriplegic or cancer patient, they tended to write the requested prescription out of empathy for the alleged 'patient.' [The group] collected Dilaudid [hydromorphone] prescriptions...diverting more than 60,000 tablets (Forgione, Neuenschwander & Vermeer 2001, p.66).

Even patients who do not engage in organised or other criminal activity can use similarly ingenious methods to access their drug of choice over and beyond their therapeutic needs. For example, a submission to this Inquiry from a former dependent user of prescription drugs states how being legitimately wheelchair bound also worked in her favour when it came to physicians or nurses acquiescing to her requests for more pain relief:

> Another form of doctor-shopping is to present at Casualty Departments in major city hospitals, and at smaller regional hospitals, including bush nursing hospitals, in rural areas.
>
> This was done by [myself] on numerous occasions during the 1980s & early '90s, specifically for pethidine injections. During this period [I] was confined to a wheelchair and used the chair as a 'prop' to gain sympathy from staff in order to obtain the drug. Even for staff who had worked in Casualty for some time,

> the *perception* of someone in a wheelchair grimacing in pain, seemed to override their usual caution.
>
> The only statement required was that [my condition] was extreme and the only drug that could ease the pain was pethidine. The statement worked.[141]

Access via the Internet

Access to prescription pharmaceuticals such as benzodiazepines and narcotic analgesics over the Internet is a relatively recent phenomenon. However, there is a growing body of evidence which shows that:

1) Large numbers of Internet sites exist on line and provide these drugs, many without the need for a prescription;
2) Many of these sites can be easily found by using standard web browsers and simple search terms;
3) Other sites show how diverted pharmaceuticals can be doctored for misuse (see, for example, Cone 2006);
4) There is case study and research evidence that both internationally and in Australia drug users are accessing these drugs online;
5) It is probable that Internet access will become a growing source of access for pharmaceutical drugs for at least a sample of illicit drug users; and
6) The Internet poses problems for authorities wanting to restrict access to these drugs for non-medical use, as the following quote from CASA highlights:

> Illegal Internet pharmacies have introduced a new avenue through which unscrupulous buyers and users can purchase controlled substances for unlawful purposes. There pharmacies – many of them based outside the U.S. – sell a variety of prescription medications including controlled drugs. Some of these pharmacies provide consumers with prescription drugs without a physical examination by a physician. The consumer fills out an online questionnaire that is reportedly evaluated by a physician affiliated with the online pharmacy. Without ever meeting the patient face-to-face, the physician approves the questionnaire and then authorizes the Internet pharmacy to send the drug to the patient. Tens of thousands of 'prescriptions' are written each year for controlled and non-controlled prescription drugs through such internet pharmacies, none of which require medical records, examinations, lab tests or follow-ups. Some of these 'rogue' internet pharmacies provide such online consultations free of charge; others refer customers to 'script' doctors who are willing to write prescriptions for cash. Finally, some internet pharmacies dispense prescription drugs without even the pretense of having a physician's prescription (CASA 2005, pp.63–64).

141 Submission to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006. The name of the author of this submission has been withheld to protect her anonymity.

In 2004 CASA conducted a study to explore the availability of controlled prescription drugs on the Internet. In a one-week period, the study identified 495 sites offering controlled prescription drugs, with 41 per cent being those drugs with the highest potential for abuse (Schedule II in the United States system). The most frequently offered controlled drugs were benzodiazepines (found on 144 sites), followed by the opioids, including drugs like hydrocodone, fentanyl and oxycodone (103 sites). Ninety-four per cent of 157 anchor sites (which sell drugs, other than portal sites which simply link to anchor sites) studied did not require a prescription. The researchers found that there were no mechanisms in place to block purchase by underage buyers. Forty-four per cent of the sites said drugs would be shipped from the United States, 20 per cent did not specify, and 47 per cent said they would be shipped from other countries (one of which was Australia). A replication of the original study, conducted one year later, found few differences. While the second study identified only 409 sites, 95 per cent of the 160 anchor sites did not require a prescription, and considerably more offered opioid medications (CASA 2005).

CASA noted that regulation is difficult because websites can appear, move, or be removed in a very short time, making it difficult to monitor or close those that are operating illegally (CASA 2005).

To ascertain the accessibility of websites offering opioid medications, Forman and colleagues (2006) conducted 47 Internet searches using Google and Yahoo with terms including 'codeine', 'no prescription Vicodin' and 'OxyContin'. More than 50 per cent of the resulting hits were sites that would sell opioids without a prescription (n=302). The study employed the standard search tools that Internet users would employ to search for information about these drugs and/or their availability on a non-prescription basis. They found that sites offering to sell opioid medications without a prescription were 'pervasive' and more prevalent than sites offering information, suggesting that the Internet seems to facilitate access to these drugs (Forman et al. 2006).

A preliminary study was conducted to gauge the extent to which people with substance use problems were accessing the Internet to purchase drugs (Gordon, Forman & Siatkowski 2006). Semi-structured interviews were conducted with 100 patients in a private drug treatment programme in eastern Pennsylvania from July 2003 to March 2004. The study found 29 per cent of patients knew that the Internet could be used to locate drugs, and nine had done so – six had purchased pharmaceuticals and three 'party drugs'. Among the total sample, the most frequently cited sources for obtaining drugs in the past month were drug dealers (77%), friends/family/colleagues (43%), health care professionals (24%), the Internet (11%), home production (6%) and theft (5%) (Gordon, Forman & Siatkowski 2006). The authors concluded that the Internet has become a source of controlled drugs for some addicted individuals.

An earlier paper in the *Medical Journal of Australia* by St George, Emanuel and Middleton (2004) provided a case example of an Australian patient who did access Schedule 8 drugs online:

> A 20-year-old patient was referred for management of anxiety and polydrug misuse. The patient related that anyone could be a misuser and pusher of drugs without relying on illicit suppliers of such drugs or "doctor shopping". A click of a mouse could supply whatever drug a patient wanted from online pharmacy services available 24 hours a day. These sites are easy to use and often require little more than a credit card number to gain access to a wide range of prescription drugs, such as diazepam, alprazolam, temazepam, methylphenidate, morphine and codeine. The patient had a 2-year history of using large amounts of zolpidem, temazepam, alprazolam and diazepam with alcohol, as well as regular use of marijuana. These medications were originally obtained by doctor shopping for prescriptions. However, while researching these medications on the Internet, our patient discovered the online pharmacies that dispensed prescription medication without a script. Zolpidem, oxycodone and methylphenidate were all ordered by the patient from online pharmacies based in Mexico and Thailand. He "surfed" the Internet for the site with the cheapest drugs and found one that sold 100 zolpidem, his drug of choice, for US$70.00, with a delivery charge of US$5.50. He was able to order quantities of 100, 200 or 500 tablets. It took 2 weeks for the discreetly packaged drugs to arrive at the patient's door. The patient volunteered this information during therapy for drug addiction and was quick to see the negative implications. After a period of counselling about the causes of medication misuse, he was motivated to cease further ordering and willing to undergo drug detoxification (St George, Emanuel & Middleton 2004, p.118).

Commenting on the above article in a *Medical Journal of Australia* editorial, Gijsbers and Whelan (2004) asked:

> What should we now do? We need more data, and cases like that described by St George et al help to alert health professionals in the field to this new drug source. The suggestions put forward by St George and colleagues have merit, but, without more data, their alarm may be premature. In the past, drug control on the supply side, especially of illicit drugs, has produced disappointing results. (Gijsbers & Whelan 2004, p.103).

Data on pharmaceutical drug detections by Customs authorities at the Australian borders suggest that levels of importation are relatively small. The Australian Crime Commission (2006) reports that in 2004–2005, Customs detected 341 unauthorised importations of benzodiazepines (down from 544 detections in 2003–2004) and only 18 detections of pharmaceutical opioids (down from 31 in 2003–2004). The majority of detections were in parcel post. There were 23 detections of postal shipments of more than 300 benzodiazepine tablets. Ten of the opioid detections involved morphine, six contained moderate quantities of

methadone, one contained codeine, and one dihydrocodeine tablets. Two postal detections contained 900 morphine capsules each.

It is difficult to know whether these statistics represent only a small fraction of the pharmaceutical drugs being mailed into the country from Internet pharmacies and other sources. In 2004, St George, Emanuel & Middleton wrote:

> We could not determine what actions these authorities were pursuing in regard to this issue. Australia Post does not have the authority to open postal articles because of privacy issues (Sal Perna, Group Manager, Australia Post, personal communication). Customs informed us that their surveillance capacity has been increased over the past 2 years to meet the challenges posed by Internet purchases of medications and other restricted goods. Customs also regularly prosecutes those who attempt to import prohibited goods without permits. At present all international mail and 70% of air cargo arriving in Australia is examined either physically or by x-ray (JH Jeffery, Acting Chief Executive Officer, Australian Customs Service, personal communication) (St George, Emanuel & Middleton 2004, p.119).

This concern was shared by Mr Steve Marty, Registrar of the Pharmacy Board of Victoria in his evidence to the Inquiry:

> There is meant to be 100 per cent X-ray scanning of mail and parcels into Australia, but th[ey] cannot possibly detect [all mail and small parcels] at the border, particularly when Customs are looking for larger things, such as container loads of pseudoephedrine that have happened in the last couple of years. Picking up a bottle of something for an individual is fairly low on the pecking order and it is very difficult to open every single pack and identify the contents.[142]

Regarding Internet pharmacies in Australia, Mr Marty was more confident about the controls in place:

> There are Internet pharmacies in Australia. We look at those websites, along with the police. Sometimes they test purchase on those. Most of them in Australia do not do it too badly...all the ones that I have looked at in fact say quite clearly up-front, 'You must have a prescription'. … It is a problem from overseas: for someone to legally be in possession, they need to have a prescription from a medical practitioner registered in the state in which they are resident. That allows them to be in lawful possession.[143]

For further discussion of Internet and mail order access to prescription drugs, see Chapter 6 of this Interim Report.

142 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, 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 Hearing, Melbourne, 19 June 2006.

143 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, 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 Hearing, Melbourne, 19 June 2006.

Summary

Although there is a lack of local studies of methods of accessing pharmaceutical drugs for non-medical use, there is enough in the international published literature and the accounts of local clinicians, regulators and others to at least gain a basic understanding of the methods used. This section has provided accounts of 'doctor shopping' the use of forged, stolen or altered prescriptions; acquisition from friends and family; diversion by pharmacy staff and other health care workers; retail theft; theft from pharmaceutical suppliers and wholesalers; access from criminals and other drug users; and finally the emerging trend of access via the Internet. However, without in-depth qualitative accounts at a local level of how these activities fit in with the broader experience of people's lives, educational, policy, regulatory and treatment responses to pharmaceutical drug misuse will be inadequate.

Case example: The non-medical use of OxyContin®[144] in the United States – lessons for Australia?

The issue of non-medical use of pharmaceutical drugs has been more prominent in the public consciousness in the United States than it has been in Australia. This is largely due to the widespread misuse of OxyContin®, a formulation of oxycodone. The development and impact of the 'OxyContin® epidemic' has been the subject of a number of United States government reports (eg. CASA, 2005; United States General Accounting Office 2003) and media stories (eg. Tough 2001). The widespread prescription of this opioid drug for treatment of non-cancer pain has been implicated in the increasing misuse of the drug in that country. With the rate of legitimate prescription and use of OxyContin® in Australia showing a similar trend (see Chapter 3), it seems timely to consider the United States experience of OxyContin® misuse.

In 1995 OxyContin® (Purdue Pharma) was approved by the Food and Drug Administration (FDA) in the United States as a sustained-release preparation of oxycodone. As OxyContin® is formulated to be released over a 12-hour period it was thought to have much lower abuse risk than immediate-release oxycodone (CASA 2005; Cicero, Inciardi & Munoz 2005).

OxyContin® was preceded by Purdue's older product, MS Contin, a morphine-based product that was approved in 1984 for pain of a similar intensity and duration and was promoted during its early years for the treatment of cancer pain (United States General Accounting Office 2003).

However, beginning in 2000, widespread reports of OxyContin® abuse surfaced (Cicero, Inciardi & Munoz 2005). Initially in Maine and in the Appalachian states of Kentucky, Virginia and West Virginia, its abuse was described as 'epidemic' in these areas (CASA 2005; United States General Accounting Office 2003).

144 OxyContin® is a narcotic analgesic – see Chapter 2, Table 2.3.

Illicit drug users had learned that by crushing the tablet the sustained release coating could be disabled and then the drug could be snorted, swallowed or dissolved in water for injection, producing an instant euphoria. As a result, OxyContin® became a popular alternative to street heroin, being termed 'poor man's heroin' or 'hillbilly heroin' (Katz & Hays 2004). In Kentucky, as elsewhere, there were notorious cases of doctors over-prescribing OxyContin®. For example, one Harlan County urologist was sentenced to 20 years in federal prison after being convicted for improperly dispensing the drug. He was seeing up to 133 patients in a day and charging them a fee of $65 each, for an OxyContin® prescription (Tunnell 2005).

> After learning about the initial reports of abuse and diversion of OxyContin in Maine in 2000, Purdue formed a response team made up of its top executives and physicians to initiate meetings with federal and state officials in Maine to gain an understanding of the scope of the problem and to devise strategies for preventing abuse and diversion. After these meetings, Purdue distributed brochures to health care professionals that described several steps that could be taken to prevent prescription drug abuse and diversion (United States General Accounting Office 2003, p.10).

By 2001, OxyContin® was the most frequently prescribed non-generic narcotic medication for the treatment of moderate-to-severe pain in the United States (United States General Accounting Office 2003). The statistics on OxyContin® prescription in the United States are presented in Chapter 3.

According to Katz and Hays (2004), since its introduction into the market place in 1995 there have been media reports of OxyContin® abuse contributing to overdose deaths, and as of 2002 there were 450 OxyContin®-related overdose deaths reported. By 2002 some 50 to 90 per cent of new methadone patients in Kentucky, Virginia, West Virginia and Pennsylvania were identifying OxyContin® as their primary drug of abuse. Yet there were also criticisms of the media portrayals of OxyContin® misuse and deaths – some claiming that mentions of OxyContin® in emergency room presentations in the United States increased in response to media stories which amounted 'to easy-to-follow instructions on the correct abuse procedure' (Butterworth 2004).

Irrespective of the mechanisms involved, the evidence is that OxyContin® abuse has spread throughout the United States, and one of the factors further fuelling its widespread diversion has been its street value of 10 times its legitimate cost (CASA 2005). Recent data collected from a project funded by Purdue Pharma for the development of an abuse surveillance programme, termed the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) system concluded that prescription drug abuse was prevalent across the country, with OxyContin® being rated by key informants as the most prevalent drug of abuse (Cicero, Inciardi & Munoz 2005).

Conversely, Purdue has also received substantial criticism in both the media (eg. Tough 2001) and United States Government agency reports (e.g. United

States General Accounting Office 2003), for what has been described as its aggressive marketing of OxyContin® in that country:

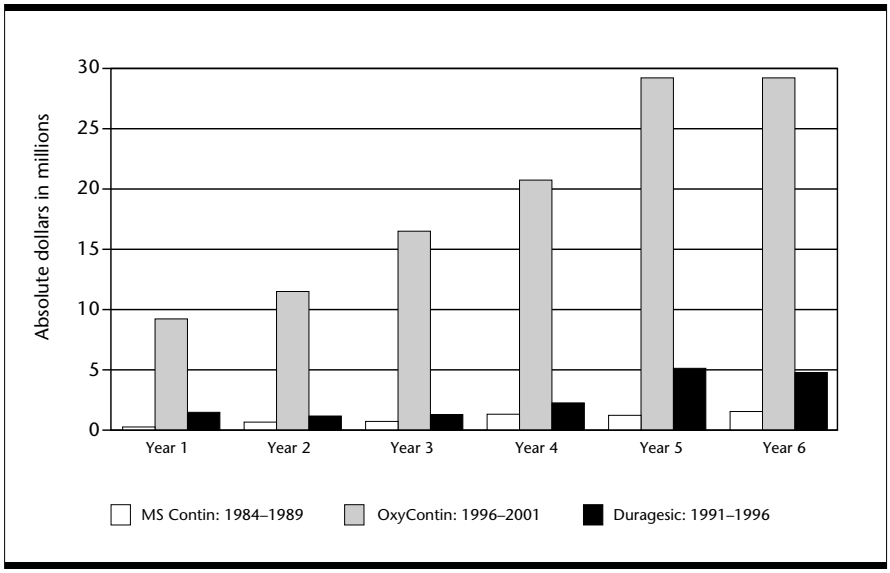
> Purdue conducted an extensive campaign to market and promote OxyContin that focused on encouraging physicians, including those in primary care specialties, to prescribe the drug for non-cancer as well as cancer pain. To implement its OxyContin campaign, Purdue significantly increased its sales force and used multiple promotional approaches. OxyContin sales and prescriptions grew rapidly following its market introduction, with the growth in prescriptions for non-cancer pain outpacing the growth in prescriptions for cancer pain. DEA [Drug Enforcement Agency] has expressed concern that Purdue marketed OxyContin for a wide variety of conditions to physicians who may not have been adequately trained in pain management. Purdue has been cited twice by FDA for OxyContin advertisements in medical journals that violated the FD&C Act. FDA has also taken similar actions against manufacturers of two of the three comparable schedule II controlled substances we examined, to ensure that their marketing and promotion were truthful, balanced, and accurately communicated. In addition, Purdue provided two promotional videos to physicians that, according to FDA, appear to have made unsubstantiated claims and minimized the risks of OxyContin. The first video was available for about 3 years without being submitted to FDA for review (United States General Accounting Office 2003, pp.16–17).

The United States General Accounting Office (2003) also points out that:

> According to DEA's analysis of IMS Health data, Purdue spent approximately 6 to 12 times more on promotional efforts during OxyContin's first 6 years on the market than it had spent on its older product, MS Contin, during its first 6 years, or than had been spent by Janssen Pharmaceutical Products, L.P., for one of OxyContin's drug competitors, Duragesic (United States General Accounting Office 2003, p.21).

Figure 5.3 below shows clearly this comparative promotional expenditure:

Figure 5.3: Promotional spending for OxyContin® and two other analgesics in the United States during their first six years of sales



Note: Dollars are 2002 adjusted.
Source: United States General Accounting Office 2003, p.22.

Originally the Food and Drug Administration in the United States permitted Purdue Pharma to imply in its labelling that OxyContin® had a lower abuse potential than other opioids because of its 12-hour time release mechanism. However, according to CASA (2005), because the time release mechanism can be subverted, as described above, OxyContin® seems to have a greater abuse potential than other opioid drugs. The original safety warning on the label, since revised in the light of Food and Drug Administration requirements, instructed users 'not to crush the pills as when crushed, toxic levels of the drug could be released'. In CASA's view 'This labelling may have suggested to drug abusers how to abuse the drug' (CASA 2005, p.21). Moreover, it has been observed that:

> The press coverage of the diversion and abuse of OxyContin has helped shape the public's perception of the magnitude of the overall problem of controlled prescription drug diversion and abuse in the U.S. and has raised considerable awareness. In response to public outcry and pressure from the DEA and FDA, Purdue Pharma adjusted some of its marketing practices, launched an educational campaign and, together with the FDA, implemented a risk management plan – aimed at detecting and preventing diversion and abuse – for the drug (CASA 2005, p.21).

According to CASA (2005) the company also employed websites to inform consumers and others about pain and associated matters. One of these sites, established in 1997, is named 'Partners Against Pain'. This site aims to provide consumers with information about options for management and treatment of pain. Notwithstanding such efforts, the Drug Enforcement Agency has criticised Purdue Pharma for not adding an antagonist agent to OxyContin® to prevent

its abuse, as has been done with buprenorphine in Australia (Suboxone) and as was done successfully in the United States with Talwin decades ago. (CASA 2005). Purdue claims to be working to change the formulation of OxyContin® to make it less able to be abused (Tough 2001). While attempts to develop narcotic analgesics with minimal abuse potential is laudable (Compton & Volkow 2006), at this stage no further information is available on Purdue's progress in this regard.[145]

OxyContin® misuse in Australia – A problem worth watching

It would seem that, to date, Australia has not experienced problems associated with the illegal and inappropriate use of OxyContin® to the same extent as the United States.[146] Nonetheless, concerns have been expressed recently that the use of this drug may become more problematic than was hitherto the case. For example, in his evidence to the current Inquiry Mr Steve Marty stated that:

> There was a 24 per cent increase in oxycodone use in the last financial year. That is a major analgesic. One of the reasons that is happening is that I think prescribers are perhaps more confident to [prescribe] narcotics than they might have been. In previous years, they thought of this as being a last resort.[147]

Dr Malcolm Dobbin of the Victorian Drugs and Poisons Unit has also indicated that this drug may become a (greater) problem in Australia than has been previously the case:

> Oxycodone is interesting. It became a major problem in the United States, particularly in the southern states, in the Appalachians, where a lot of older miners with back problems started being prescribed oxycodone, particularly the brand name OxyContin®. These people then found that they could sell them to injecting drug users and started trading them. Then people started drug seeking for OxyContin® and there were a lot of deaths associated with OxyContin®. It became known as 'hillbilly heroin' when ground up. The sustained preparation is supposed to supply the dose for a day or over 12 hours. Instead of taking one tablet three times a day you can take one tablet. People would grind up these high-dose tablets and either snort them or inject them, together with other drugs, as in most of the deaths. There were a number of

145 There have been a number of legal actions filed in United States courts against the company: 'According to Purdue, as of early October 2003, over 300 lawsuits concerning OxyContin were pending against Purdue, and 50 additional lawsuits had been dismissed. The cases involve many allegations, including, for example, that Purdue used improper sales tactics and over-promoted OxyContin causing the drug to be inappropriately prescribed by physicians, and that Purdue took inadequate actions to prevent addiction, abuse and diversion of the drug. The lawsuits have been brought in 25 states and the District of Columbia in both federal and state courts' (United States General Accounting Office 2003, p.10).

146 Statistics on the growth of OxyContin® prescriptions in Australia (and the United States) are presented in Chapter 3. In Australia OxyContin® is produced and marketed by Mundipharma Pty Ltd, an associate company of Purdue. See www.mundipharma.com.au.

147 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, 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 Hearing, Melbourne, 19 June 2006.

> deaths associated with that. There is a potential for oxycodone to become much more of a problem in Australia and Victoria.[148]

In 2005, due to anecdotal reports about increasing use of oxycodone among IDUs, questions were specifically added about oxycodone to the survey of Australian injecting drug issues conducted annually as part of the IDRS (Stafford, Degenhardt, Black et al. 2006). In 2005, 15 per cent of Victorian IDUs surveyed as part of the IDRS said they had injected oxycodone in the previous six months, with OxyContin® being the most commonly used product (Jenkinson & O'Keefe 2006).

The activities of drug users, treatment providers, regulators, pharmaceutical companies and the media in the example of OxyContin® misuse in America is one that should inform the response to non-medical use of this and other pharmaceutical drugs in this country.

Conclusion

This chapter provided an overview of the reasons why people use benzodiazepines and narcotic analgesics for non-medical purposes and how they access these drugs. While the abuse of these drugs seems far from the experience of many Australians, the reasons people do this are, from their perspective, rational and understandable. Consideration of the way these drugs are accessed reveals the challenges posed to regulators, professional associations, the private sector and individual health professionals.

Compared to other drug problems in Australia, there is a dearth of information on the culture of non-medical use of pharmaceutical drugs. While the international literature, drug trends monitoring provided by the IDRS, and submissions provided to this Inquiry provide a reasonable sense of how these drugs are accessed and the reasons for their misuse, this is an issue that will need attention in a full Inquiry. Clearly there is a need for further research on this issue. Without in-depth qualitative accounts at a local level of how these activities fit in with the broader experience of people's lives, educational, policy, regulatory and treatment responses to pharmaceutical drug misuse will be inadequate. This chapter has also suggested that a watching brief will need to be kept on two areas which have emerged from United States reports on the misuse and abuse of pharmaceutical drugs, namely 'pharming parties' and the escalating misuse of OxyContin®.

While there is relatively little information available on the extent to which OxyContin® is abused in this country, it is an issue that needs to be monitored by the Victorian Drugs and Poisons Unit and other relevant agencies. It is also

148 Dr Malcolm Dobbin, Senior Medical Adviser, Drugs Policy and Services, Department of Human Services, Briefing given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 29 May 2006.

an issue that this Committee will explore further in its ongoing consideration of prescription drug abuse.

Questions for further consideration

To what extent is overseas information on reasons for non-medical use of pharmaceutical drugs relevant to the Australian and Victorian experience?

To what extent is overseas information on methods of accessing pharmaceutical drugs for non-medical use relevant to the Australian and Victorian experience?

Is there a need for in-depth qualitative research of non-medical use of prescription drugs from a user's perspective, both in Victoria and nationally?

Can illicit drug monitoring systems such as the Illicit Drug Reporting System and the Party Drugs Initiative be modified or enhanced by qualitative data collections looking at emergent topics such as pharmaceutical drug misuse?

To what extent does the activity of pharmaceutical companies contribute to non-medical use of pharmaceutical drugs and are they actively engaged in this country in contributing to reducing the harm caused by this misuse?

What lessons can be learned from the United States' experience with OxyContin® misuse that could inform strategies to prevent similar problems with the drug in this country?

Is increasing non-medical use of pharmaceutical drugs a likely consequence of successful strategies to limit supply of illicit drugs, and what are the implications of that for drug users and the wider community?

What are the experiences of pharmaceutical drug misuse in countries that have prescription heroin available to heroin dependent people? Specifically, what are the impacts on users, doctors and pharmacy staff? Have there been impacts on rates of 'doctor shopping', 'scamming' for prescriptions, or pharmacy theft, robbery and break and enter offences?

What are the harm-reducing elements of non-medical use and what might be some of the unintended consequences of implementing strategies to further curtail the practice?

6. Legal and Regulatory Issues Pertaining to Benzodiazepines and Other Pharmaceutical Drugs

> The structures of drug regulation that exist today – drug laws, drug regulatory agencies, drug evaluation boards, quality control (QC) laboratories, drug information centres, etc. – have evolved over time. During this process, the scope of legislative and regulatory powers has been gradually expanded, in response both to the ever-increasing complexity of an increasingly sophisticated pharmaceutical sector, and to the perceived needs of society. In some countries the enactment of comprehensive drug laws was a result of crisis-led change, when public demand led to the adoption of more restrictive legislation to provide stronger safeguards for the public. Drug regulation is therefore a public policy response to the perceived needs of society. Consequently, drug laws need to be updated to keep pace with changes and challenges in their environment (World Health Organization (WHO) 2002, pp.1–2).

The system of drug regulation in Australia today is comprehensive, if not complex. This chapter traces the evolution of drug regulation in Australia and Victoria, the current modes of control and suggested recommendations for reform. It also examines the regulatory framework that governs the way in which pharmaceutical drugs enter the market. This system is for the most part jointly administered through Commonwealth and state authorities. The various and overlapping responsibilities between Commonwealth and state/territory authorities and the laws they administer is presented in Figure 6.1.

Table 6.1: Commonwealth and state responsibilities for medicines and drugs control in Australia

Commonwealth

Law or Instrument	Remarks
• Commonwealth Constitution Section 51 (i) Interstate Trade Section 51 (xx) Corporations Section 51 (xiiiA) Pharmaceutical benefits Section 51 (xxix) External affairs	Gives the Commonwealth exclusive powers to regulate in the field of drug control where the actions cross jurisdictional boundaries and fall within relevant listed powers under Section 51. Other regulatory interventions or models must be adopted by reference or through mirror legislation into state law.
• *Therapeutic Goods Act 1989*	The *Therapeutic Goods Act* established the Therapeutic Goods Administration (TGA), which governs the listing process for most drugs and medicines in Australia, the licensing of drugs manufacturers and administers the laws and policies with regards to advertising, labelling and packaging of medicines and other drugs and poisons at a national level.
• Therapeutic Goods Regulations 1990	Supplements the *Therapeutic Goods Act* with more detailed administration procedures and processes
• Therapeutic Goods Orders	Orders made by the Minister under section 10 of the *Therapeutic Goods Act*. These orders specify the standards or directives for therapeutic goods.
• Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)	The SUSDP is drawn up by the National Drugs and Poisons Schedule Committee and is issued by the Australian Health Ministers' Advisory Council (AHMAC). It is adopted by reference or mirror legislation into state and territory legislation.
• Therapeutic Goods Advertising Code (TGAC) 2006	The Code ensures the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods.
• Various Therapeutic Goods Administration Committees	See Figure 6.2 for a list of these supplementary committees and agencies and their functions.

Victoria

Law or Instrument	Remarks
• *Therapeutic Goods (Victoria) Act 1994*	State 'mirror' legislation that complements and adopts most of the provisions of the *Therapeutic Goods Act 1989* (Commonwealth). In particular, it incorporates procedures with regard to listing and registration and evaluation of therapeutic goods in Victoria.
• Drugs Poisons and Controlled Substances Act (DPCSA) 1981	
- Division One	• Poisons List and Poisons Code adopts Commonwealth standards with regard to drug scheduling.
- Divisions Four and Ten	• Administers and governs issuing of permits and licences to prescribe, dispense or administer scheduled drugs of dependence. Generally regulates prescribing and administration of Schedule 4, 8 and 9 poisons including prescription medicine offences.
- Part Five	• Provides for criminal law offences and penalties with regard to drugs of dependence.
• Drugs Poisons and Controlled Substances Act Regulations 2006	Supplements the DPCSA with more detailed prescription regulations controlling the administration of drugs and poisons in Victoria.
• *Road Safety Act 1986* – Section 49 (i) (ba)	Provides for an offence of driving a motor vehicle while being drug impaired (includes prescription drugs).
• *Road Safety (Drug Driving) Act 2003*	Provides for random breath testing of suspected drug drivers comparable to alcohol breath testing. Currently only applies to certain illicit drugs.

The chapter is primarily concerned with the legal framework pertaining to the production, administration and use of benzodiazepines and other pharmaceutical drugs, whereas the following chapter more specifically pertains to the way in which the governing laws and regulations are administered or followed in practice.

The first section of the chapter looks at the role of the Therapeutic Goods Administration (TGA), the process of *scheduling* drugs and drug licences. It also looks briefly at the regulations and processes surrounding their advertising, labelling, and storage and recording mechanisms. A key aspect of this section is a discussion of the *Review of Drugs, Poisons and Controlled Substances Legislation* (hereinafter called the Galbally Review).

It should be noted at the outset that this is a very complex area of regulation that is frequently subject to change and review. The review of pharmaceutical drug regulation in this Interim Report is by necessity basic, drawing only upon the most essential features of the current framework.[149]

The second part of the chapter discusses the various controls that have been put in place at state level to ensure that drugs such as benzodiazepines are used only for the purposes for which they were produced. While the Commonwealth legislation is primarily concerned with the safety of the product per se, state regulation is more concerned with the way in which the product is used and, if it is a prescription medicine, how it is prescribed. It examines the law in this area from both the perspective of those who prescribe and dispense the drugs, in addition to those who use (and abuse) them. The key legislation in this area is the *Drugs, Poisons and Controlled Substances Act 1981* (DPCSA) (as amended) and the recently reformulated regulations issued under that Act.[150] Guidelines and Directions issued by both the Drugs and Poisons Unit (DPU) of the Victorian Department of Human Services (DHS) and those formulated by professional bodies and associations, such as the Pharmacy Board of Victoria, are also relevant in this context.

This part of the chapter provides the legal background and context for the discussion in Chapter 7 pertaining to the interventions and programmes used by pharmacists, medical practitioners and regulatory bodies to combat abuse of pharmaceutical drugs in Victoria.

Finally, the chapter briefly examines some more general aspects of the criminal law as it applies to these drugs. Included in this discussion is a brief account of the legal provisions associated with the use of pharmaceutical drugs when driving a car or other motor vehicle.

149 For example, the combined length of the *Therapeutic Goods Act 1989* and its associated regulations is over 600 pages, not including associated guidelines, appendices, codes and other related documents.

150 See Drugs, Poisons and Controlled Substances Regulations 2006.

Commonwealth and state regulation of pharmaceutical drugs in Australia

The legislative regulation of pharmaceutical drugs, poisons and controlled substances reflects a concern that a system where there are no controls over these drugs would lead to consumers being at risk:

> As the use of such substances grew, and as concern over their misuse developed, official controls were increasingly introduced (Galbally 2000b, p.151).

Before examining the legal mechanisms pertaining to Australian drug regulation in detail it is necessary to place such a review in its historical and philosophical context.

History of drug regulation in Australia

It is thought that the first legislative control of drugs and poisons in England (and by extension the Australian colonies) was through the *Arsenic Act 1851* (Jones 2000).[151] Over the next 100 years a series of pharmacy, drug regulation and poisons Acts were enacted in the Australian states federated in 1901. These legislative instruments increasingly regulated at local level the manufacture, distribution, sale and quality of medicines, drugs and other pharmaceutical goods.[152]

Thus, prior to the Second World War any controls over the distribution and retailing of drugs were primarily the responsibility of state governments and there was only limited concern with drug evaluation (Industry Commission 1996a, p.42).[153] The first committee to advise on the evaluation of pharmaceutical drugs was established by the state of Victoria in 1948 (WHO 2002, p.35). This Committee, however, could only review those products sold within the state boundaries of Victoria.

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151 In the mid 19th century, death from poisoning was a major cause of mortality. Arsenic was often implicated as the causative agent. As a result, in Britain the then newly incorporated Pharmaceutical Society, together with the doctors, lobbied for the government to introduce legislation on this subject (Jones 2000):
'The Arsenic Act of 1851 resulted and was the first measure introduced in an attempt to control the sale of any poisonous substance. A record of the transaction was to be made in a book which both vendor and purchaser would sign. The Act applied only to arsenic. Sales were not restricted to premises occupied by the newly emerging chemists and druggists and it appeared that any trader could sell it, provided a record was kept' (2000, p.938).
The Arsenic Act in turn led soon after to the Pharmacy Act of 1868 and the colonial Australian equivalents.

152 For a general account of the history of pharmacy and pharmaceutical regulation in Australia, see Miller 2005. For a review of the history of drug regulation from a British perspective generally, see Griffin and Shah 2006.

153 While the Commonwealth Department of Health was established in 1921, most health-related regulation was the province of the states until the early 1950s. In 1953 the *Therapeutic Substances Act* was enacted giving the federal government control over imported therapeutic substances, drugs of addiction and the interstate trade of these substances (Hirshorn & Monk 2006, p.653).

In the 1950s, limited drug evaluation procedures were introduced at Commonwealth level by the National Biological Standards Laboratory.[154] Tests were undertaken to ensure therapeutic goods complied with applicable standards in the United Kingdom.[155]

Arguably, however, the most important event that led to more stringent systems of pharmaceutical control both in Australia and worldwide was the thalidomide crisis of the early 1960s.[156] As a result of the crisis, the Australian Drug Evaluation Committee (ADEC) was established in 1963:

> The thalidomide experience had brought home to Australian health officials that there were not only benefits but [also] potential risks from the use of therapeutic compounds…The role of the Committee in the genesis of Australia's drug regulatory system was pivotal. It was as a result of the recommendations of the Committee that standards for submission of data for people wishing to import medicines into Australia were introduced. The Committee also sought to ensure that companies were required to provide information about risks, as well as benefits, in promotional material for health professionals and very early in its life established a voluntary adverse drug reaction reporting scheme (TGA 2003, p.1).[157]

Since 1963 a range of Commonwealth bodies, agencies and committees, many with state jurisdictional representation, have been established to coordinate and oversee drug evaluation and controls in Australia. A list of these bodies is shown as Figure 6.2.[158]

154 The relevant constitutional authority giving the Commonwealth legal powers over pharmaceutical drug regulation (across state borders) is found in Section 51 of the Commonwealth Constitution, particularly S 51(1) [inter state trade]; S 51 (xx) [corporations]; S 51 (xiiiA) [pharmaceutical benefits] and S 51 (xxix) [external affairs].

155 Particularly those standards based on the *British Pharmacopoeia*, the definitive source of pharmaceutical standards. This source is still used and incorporated by reference as the definitive standard in Australian Commonwealth and state legislation to this day.

156 The use of the sedative drug thalidomide partly to address nausea and 'morning sickness' during pregnancy resulted in the birth of children with body abnormalities and malformations on an unprecedented and worldwide scale. The drug was withdrawn from use in most countries by the end of 1961. For a general discussion of the thalidomide crisis, see Griffin and Shah 2006; Clow 2003; and Porter 2006.

157 This later evolved into a formal subcommittee of the TGA, the Adverse Drug Reactions Committee. See discussion below.

158 This is by no means an exhaustive list but it does outline the most important of the Commonwealth and joint Commonwealth and state/territory bodies.

Table 6.2: Committees and agencies associated with drug regulation

The **Australian Health Ministers' Advisory Council** (AHMAC). Membership comprises the Head (plus one other senior officer) of each of the Australian Government, state and territory and New Zealand health authorities, and the Australian Government Department of Veterans' Affairs. AHMAC approves the Standard Uniform Schedule for Drugs and Poisons.
The **National Coordinating Committee on Therapeutic Goods** (NCCTG) comprises representatives from Commonwealth and state health authorities and makes recommendations to the Australian Health Ministers' Advisory Council.
The **Australian Register of Therapeutic Goods** (ARTG) was established under the *Therapeutic Goods Act 1989*. The ARTG is a computer database of therapeutic goods. Therapeutic goods are divided into two major classes: medicines and medical devices. Unless exempt, therapeutic goods must be entered as either 'registered' goods or 'listed' goods before they may be supplied in or exported from Australia.
The **Australian Drug Evaluation Committee** (ADEC) is the statutory body under the *Therapeutic Goods Act 1989* that advises the Minister and the Secretary of the Department of Health and Ageing (DoHA) on which products are to be entered onto the ARTG.
The **Therapeutic Goods Administration** (TGA) is a Division of the DoHA. It provides administrative support to ADEC and acts as the national therapeutic goods control authority.
The **Medicines Evaluation Committee** (MEC) is an expert committee that provides advice to the Secretary of the DoHA on the registration of over-the-counter or non-prescription drugs (other than traditional medicines).
The **Complementary Medicines Evaluation Committee** (CMEC) is an expert committee that provides advice to the Secretary of the DoHA on the registration of non-prescription traditional medicines.
The **Adverse Drug Reactions Advisory Committee** (ADRAC), a sub-committee of ADEC, monitors the safety of therapeutic drugs when released on the market.
The **National Drugs and Poisons Schedule Committee** (NDPSC) recommends scheduling restrictions for adoption by the states. It consists of Commonwealth, state and territory government representatives and technical expert members. It reports to AHMAC, and is supported administratively by the DoHA.

The establishment of the National Coordination Committee on Therapeutic Goods in the 1970s in conjunction with the National Drugs and Poisons Schedule Committee (NDPSC) was particularly important in creating a mechanism for achieving some degree of uniformity in therapeutic goods legislation across Australian jurisdictions.[159]

Arguably the most important change to the joint Commonwealth–state regulatory system in recent years was the enactment of the *Therapeutic Goods Act*

159 Although, as the *Galbally Review* has commented, this has not always been successful. Differences between state legislation and between some state legislation and the Commonwealth model remain to this day, although these will diminish as the recommendations of the Review are gradually implemented (Galbally 2000a, 2000b). See also discussion below.

1989. This Act, its subsequent amendments, and the body primarily responsible for its administration (TGA)[160] form the basis for regulatory control of drugs and therapeutic substances in Australia.[161]

The augmentation of stricter drug control policies is a classic case of 'crisis led change' (WHO 2002, p.37). Increasingly, and certainly since the thalidomide crisis, effective drug regulation has also had an international profile with the WHO and other international agencies providing support to supplement national regulatory efforts.[162] Drug control, particularly with regard to narcotics, has been increasingly harmonised with the creation of international treaties and instruments to facilitate cross-border drug controls and, in some cases, regulate prescription medicines.[163] For example, additional restrictions for prescribing, dispensing and administration will apply to certain drugs over and above those of other prescription drugs, subject to United Nations conventions.[164] Closer to home the creation of the Trans Tasman Treaty Agreement establishing a single regulatory agency for therapeutic products that

160 The TGA has had an interesting history. It has been transformed from originally being a government funded to a self-funded agency. Since the 1980s fees and charges for the evaluation of applications have increasingly become the source of income of the administration.

161 As will be discussed later in this chapter, the jurisdictional and legal basis by which the provisions of this Commonwealth legislation is incorporated into state and territory law is complex and beyond the scope of this chapter. Suffice to say that some states may incorporate the whole Act or parts thereof by reference into its own legislation, while others such as Victoria may pass mirroring legislation. Whatever method is chosen, for the most part drug regulation is remarkably similar across the states and between the states and the Commonwealth. The *Galbally Review* of drug regulation legislation has, however, recommended central and uniform model Commonwealth drug legislation that, if the states adopt, may mean them ceding some of their powers. See discussion later in this chapter.

162 Particularly in developing countries. As with so many areas of health policy, regulation and development it is the countries of the industrialised west that have the most well developed drug regulation systems. Despite the efforts of international agencies, 'Generally, in most developing countries, drug regulation is very weak and the safety, efficacy and quality of imported or locally manufactured drugs cannot therefore be assured' (WHO 2002, p.11).

For an interesting comparative account of global drug regulation systems see the report *Effective Drug Regulation: A Multi-country Study* (WHO 2002). This study of 10 countries (including Australia) from a variety of geographic regions, cultural and socio-economic backgrounds compares and assesses drug regulation performance and efficiency in these countries using a standardised methodology 'to document the results so that other countries may learn from them' (WHO 2002, p.11).

163 In particular Australia is a signatory to the Single Convention on Narcotic Drugs 1961, the Psychotropic Substances Convention 1972 and the Illicit Trafficking of Narcotic Drugs and Psychotropic Substances Convention 1988. Australia has also developed formal processes through the *Therapeutic Goods Act* and regulations to adopt international guidelines on drug control such as those of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Australia also has membership of international bodies devoted to developing best practice drug regulation policies such as the Pharmaceutical Inspection Convention. From the producer side, Australian pharmaceutical companies may be members of international peak bodies and lobby groups such as the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). The internationalisation of drug policy, while an interesting and important topic, is beyond the scope of this chapter (see generally Griffin & O'Grady 2006).

164 Usually listed as Schedule 8 drugs in Australia. See discussion below.

will cover both New Zealand and Australia and its states is a good example of a bilateral agreement on harmonising drug policy in a particular region.[165]

The objects of drug regulation

> In drug regulation, the government acts as the guardian of the public by controlling private powers for public purposes. Ensuring the safety, efficacy and quality of drugs available to the public is the main aim of drug regulation…Drug regulation is the totality of all measures – legal, administrative and technical – which governments take to ensure the safety, efficacy and quality of drugs, as well as the relevance and accuracy of product information. Public health and safety concerns have obliged governments to intervene in the activities of the pharmaceutical sector.
>
> Guaranteeing the safety, efficacy and quality of drugs available to the public is the main goal of drug regulation and encompasses a variety of functions. Key functions include licensing of premises, persons and practices; inspection of manufacturing facilities and distribution channels; product assessment and registration (marketing authorisation); adverse drug reaction monitoring; control of drug promotion and advertising. Each of these functions targets a different aspect of pharmaceutical activities, but all of them must be undertaken simultaneously to ensure effective consumer protection (WHO 2002, pp.4–5, 7–8).

Since the turn of the twentieth century an extraordinary development in the range, number and effectiveness of pharmaceutical products has taken place. Most of these drugs, including the benzodiazepines, have provided great benefits to society. The downside, however, has been the increase in the number of toxic, impure, untested, substandard and counterfeit drugs on national and international markets and the terrible consequences of these that may occur (WHO 2002).[166]

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165 The ultimate aim of the agreement is to work towards the complete harmonisation of the regulatory system for therapeutic goods in both countries. The single regulatory agency is expected to commence operations in late 2006.

In 2005 Australia also entered into a trade agreement with the United States with regard to the free trade of medicines and pharmaceutical drugs. The development of the Australia–United States Free Trade Agreement (AUSTFA) has not been without controversy, particularly with regard to the effects it may have on the Pharmaceutical Benefits Scheme and the National Medicines Policy. Such a topic, however, is beyond the scope of this Inquiry. For further discussion, see Faunce et al. 2005. For an interesting discussion of the comparative systems of drug regulation in Australia as compared to the United States, see the transcript of the *Health Report* (12 June 2006). In this discussion between Australian and American health academics it was generally agreed that the Australian Therapeutic Goods Administration is far less influenced by the pharmaceutical industry than its American equivalent, the Food and Drug Administration.

166 Most discussion of drug regulation recognises, however, that a balance needs to be maintained between safeguarding the public health by stringently evaluating and licensing drugs and yet at the same time promoting public health by making potentially valuable drugs available without unnecessary delay. Indeed the *Baume Review* established in 1991 aimed at better balancing the interests of speedy assessment and availability of pharmaceuticals and safety issues, particularly in the context of HIV/AIDS-related drugs. As a result the concept of 'timely availability' (of drugs) was added to the objectives of the *Therapeutic Goods Act* (see Baume 1991; Industry Commission 1996a).

Given these developments, the primary objective of drug regulation is to redress 'the market failure arising from the *asymmetry of information* (knowledge and understanding) of the risks and hazards associated with consumer access to and use of poisons' (Galbally 2000a, p.15). As such, it is appropriate in certain circumstances to restrict the free market in the production and trade of such goods in the interest of public health.[167]

However, different countries and political systems, even within the industrialised democracies, promote different levels of drug regulation. For example, in some countries herbal, naturopathic and vitamin products may be strictly regulated while in others, including Australia, they may not be. In some countries self-regulation of pharmaceutical production through the use of codes of practice may be common, at least with some types of drug, while other countries may require more stringent regulation through government boards of control. Some nations may manufacture and distribute drugs and others, including Australia, may leave manufacturing to private pharmaceutical companies subject to them complying with government mandated quality controls. Finally, different systems of regulation will place different emphasis on the role of the private sector in the regulatory process generally. Australia, for example, is one of the few countries in which pharmaceutical company and consumer group representatives have a formal place 'at the table' of government advisory committees such as those under the auspices of the TGA. Indeed, according to the WHO, Australia is the only country that allows pharmaceutical industry representatives to deliberate on committees that have power to consider evaluation or registration applications.[168]

The regulatory system for pharmaceutical drugs (including prescription drugs) in Australia is generally seen as one of the better global models of regulation (WHO 2002). Moreover, the need for regulation of pharmaceutical products to ensure the safety and efficacy of therapeutic goods has generally been accepted, and indeed promoted, by the health sector, consumers and the pharmaceutical

167 Even where this may conflict with national competition policy. The *National Review of Drugs, Poisons and Controlled Substances Legislation* (the Galbally Review) commissioned to examine national and state drug regulation legislation and practices in light of the National Competition Policy recognised that drugs and poisons, while often highly valuable to the community, 'can and do result in harm and that this would be expected to worsen under unrestrained deregulation' (Galbally 2000a, p.ix). The Review concluded: 'the total potential for harm warrants acceptance of reduced competition and higher costs in some circumstances' (Galbally 2000a, p.ix). For further discussion of the Galbally Review, see later in this chapter.

168 The World Health Organization for example discusses the importance of both consumer and industry bodies in the development of drug regulation policy in Australia. Bodies such as the Consumers Health Forum (particularly since the advent of HIV/AIDS), Medicines Australia, the peak body for Australia pharmaceutical companies, and professional peak bodies such as the Pharmacy Guild of Australia and the various Royal Colleges of Medicines all play an important role in contributing to the policy debate on drug regulation in Australia (WHO 2002). The Australian Pharmaceutical Advisory Council (APAC) is a good example of a body that has input from a wide range of stakeholders, including medical, industry and consumer representatives with the aim of advising the Commonwealth Minister of Health on pharmaceutical policy and regulation. For further information on APAC, see their website at http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/nmp-advisory-apac.htm

industry alike (Industry Commission 1996a, p.41). A discussion of this system is the subject of the next section of this chapter.

Drug regulation in the modern era: The Therapeutic Goods Act 1989 and associated legislation

Other legislation and policies affecting drug regulation

It should be stated from the outset, that while the focus of this section is appropriately on the operations of the *Therapeutic Goods Act* and complementary state legislation, the overall system of drug regulation in Australia is affected by a number of other legislative and policy provisions extraneous to this specific legislation. These will be canvassed briefly before proceeding to a detailed discussion of the *Therapeutic Goods Act*.

From a legislative perspective a range of Acts and regulations also have bearing on the overall issue of drug regulation. These may include laws with regard to customs and imports,[169] consumer protection legislation,[170] trade agreements,[171] agricultural and veterinary laws,[172] criminal legislation,[173] occupational health and safety,[174] and regulations pertaining to food standards.[175] Such legislation may also be duplicated or supported, at least in part by state and territory equivalents.

In addition to legislation, drug regulation may be affected by a variety of national and state policies. One of the most important of these is the federal Pharmaceutical Benefits Scheme or PBS. The PBS is the national scheme

169 *Customs Act 1901* and associated regulations.

170 *Trade Practices Act 1974*.

171 For example, the *Trans Tasman Mutual Recognition Act 1997*. See also the *US Free Trade Agreement Implementation Act 2004*.

172 *Agricultural and Veterinary Chemicals Code Act 1994*.

173 *Narcotic Drugs Act 1975*.

174 At state level the adverse effects of drug use, including prescription drug use, are covered in the *Occupational Health and Safety Act 2004* (Vic). Correspondence to this Inquiry by Mr John Lenders, the Victorian Minister for WorkCover, states that while the Victorian WorkCover Authority has not specifically covered activities or programmes relating to prescription drugs, the general principles of the OHS Act require:

- Employers to provide and maintain a working environment that is safe and without risks to health and safety
- Employers and self-employed persons to ensure that persons other than employees are not exposed to risks to their own health arising from the undertaking of the employer or self-employed person
- Employees to take reasonable care for their own health and safety and that of others (for example, ensuring that they are not by use of drugs, affected in a way that may put themselves or others at risk).

These requirements may from time to time result in employers promoting or implementing programmes such as prevention, education, counselling and rehabilitation initiatives to address drug issues in the workplace as part of an overall OHS strategy. Conceivably such a strategy could include materials with regard to prescription drug abuse and particularly the consequences for worker fatigue and safety issues (See correspondence of Mr John Lenders, Minister for WorkCover, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006).

175 *Australia New Zealand Food Authority Amendment Act 2001*.

whereby certain listed prescription or hospital-administered medicines are subsidised by the state. The PBS is predominantly concerned with the timely access by Australians to low cost medicines rather than their regulation per se.[176] As such, a detailed discussion of the scheme is beyond the scope of this chapter. What is of relevance, however, is the fact that some of the federal and state safeguards with regard to the use and abuse of prescription drugs apply only to PBS listed drugs. In other words, there may be situations in which a person accesses drugs outside of the PBS, for example by private payment, and thereby bypasses some of the safeguards built into the system to prevent 'doctor or prescription shopping', an issue discussed in Chapter 5.

The National Medicines Policy is another federal policy that impacts upon drug regulation. Although extending beyond prescription medicines to complementary healthcare and over-the-counter products, the overarching aims of the policy implemented in 2000 are based on the following objectives:

- Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- Medicines meeting appropriate standards of quality, safety and efficacy;
- Quality use of medicines; and
- Maintaining a responsible and viable medicines industry (Commonwealth of Australia 1999, p.1).

It is the third arm of the National Medicines Policy that is particularly relevant to the issue of drug regulation. The Quality Use of Medicines Program is concerned that the quality, safety and efficacy of medicines available in Australia should be of the highest possible standard. While agencies such as the TGA are responsible through the mechanisms outlined below for the quality of the drugs released in Australia, their correct prescription, dispensation, use and administration is promoted through both education campaigns aimed at doctors, nurses, pharmacists and consumers, formal agreements between government and providers such as the Community Pharmacy Agreements[177] and the professional codes of practice of groups such as the College of General Practitioners, the various state Pharmacy Boards,[178] and the Codes of Practice governing the Australian pharmaceutical industry, particularly that of the industry's peak body, Medicines Australia. These are matters that are more suitably developed in Chapter 7 of this Interim Report.

176 For a comprehensive account of Australia's PBS, see Duckett 2004.

177 Since 1990 the Commonwealth of Australia and the Pharmacy Guild of Australia (PGA) have entered into five-year Community Pharmacy Agreements (CPA). While the agreements primarily set out the remuneration scales for pharmacists dispensing under the PBS, the current (Fourth) CPA also makes arrangements for the provision and funding of professional pharmacy programmes including services enabling pharmacists to better educate and instruct their customers with regard to the medications they have been prescribed. See *Fact Sheet* Community Pharmacy Agreements at http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pharmacy-4cpafact

178 For a discussion of the important role these professional bodies play in the administration of prescription and other drugs, see Chapter 7.

The Therapeutic Goods Act 1989

The *Therapeutic Goods Act* (hereinafter the Act) is the basis of modern drug regulation in this country and through some complicated legal mechanisms by extension to the states.

When enacted in 1989 the Act and its regulations were instrumental in giving the Commonwealth more clearly delineated regulative authority over pharmaceutical and other drugs. As Hirshorn and Monk state, the Act applies to:

- All corporations who supply or manufacture medicines for supply (regardless of where) in Australia
- Unincorporated parties who supply or manufacture medicines for supply in Australia outside their own state or territory
- All parties (whether incorporated or unincorporated) who supply medicines under the Pharmaceutical Benefits Scheme (PBS)
- All parties (whether incorporated or unincorporated) who import or export medicines (2006, p.655).

Complementary state or territory legislation is necessary in those circumstances where activities fall solely within the boundaries of the state or in areas where state governments have sole responsibility.[179]

The increasing 'nationalisation' of drug regulation and policy recognises the changing circumstances over time whereby originally:

- Protecting public health was viewed as a State responsibility, not a matter for national policy.
- There was no Commonwealth legislation established for evaluating products.
- Emphasis was on substances, and is now more on products. Often the substance was the product, whereas now the same substance can be used in different products, in different strengths, combined with other ingredients, in different packaging, and intended for different uses.
- Consumer access was limited to the physical presence at retail outlets, whereas now there is increased access through distance supply mechanisms, such as the Internet.
- Comparatively fewer substances and less diverse products were available than are now, especially those intended for aged care (Galbally 2000b, p.28).

The objectives of the controls under the Act are based on the assumption of knowledge or information asymmetry:

179 As the Galbally Review comments, local government plays very little if no role in the regulatory aspects of drug or medicines control (Galbally 2000b, p.152).

> [n]ot only are consumers not fully informed about the consequences of their choices but…often it would be difficult for them to independently gain an adequate knowledge and understanding of:
>
> - The substances and products needed to treat particular conditions;
> - The risks associated with particular substances;
> - The way in which products containing the substances need to be used safely and to achieve optimal health benefits;
> - The potential interactions with other medicines or foods;
> - Contraindications with certain medical conditions; and
> - Poisonous substances that may be very dangerous if used inappropriately, whether intentionally or unintentionally (Galbally 2000a, p.13).[180]

Under the Act, controls include but are not restricted to the main areas of the scheduling, licensing, advertising,[181] labelling[182] and record keeping of certain drugs[183] and pharmaceutical products.[184]

Drug listing and registration

The Drug Safety and Evaluation Branch of the TGA evaluates prescription medicines for inclusion on the Australian Register of Therapeutic Goods (ARTG).[185] A sponsor makes an application to TGA to have his or her substance listed on the register as either a *listed* or a *registered* good if it is to be imported, exported, manufactured or supplied in or from Australia. Registered products

180 The *Galbally Review* recommended that the types of objectives for both the general regulatory drug framework and scheduled medicine controls in particular be specifically set out in Commonwealth and state legislation. See in particular Recommendations 1 and 3 of the Review (Galbally 2000a, p.xiv).

181 See discussion below.

182 The labelling of medicines in Australia must conform with directives and regulations of the TGA. In particular the directive Therapeutic Goods Order 69 *General Requirements for Labels for Medicines* specifies that information must provide the names and quantities of active ingredients, expiry dates, identification of inactive ingredients and label size, to mention a few. Labels must also conform to the requirements of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and associated schedules, particularly the requirements for schedule signal headings. For further discussion of labelling requirements see Hirshorn and Monk 2006, p.681.

Another way of addressing the issue of information asymmetry between producers and consumers is through the use of Product Information (for health professionals) and Consumer Medicine Information (for consumers). For a discussion of these requirements, see Hirshorn and Monk 2006, pp.666–667 and the discussion in Chapter 8 of this Interim Report.

183 The *Therapeutic Goods Act 1989* also governs the control of certain 'medical devices' such as an instrument, appliance or article to be used inter alia for the diagnosis, prevention, monitoring, treatment or alleviation of disease, the control of conception and the investigation, replacement or modification of the anatomy or of a physiological process. See *Therapeutic Goods Act 1989*, Section 41BD.

184 There are also provisions with regard to counterfeit goods and tampering of goods, gene technology, product recalls, and criminal and civil offences and penalties imposed for infringement of the Act and regulations. A discussion of these provisions is beyond the scope of this chapter.

185 Therapeutic Goods are defined in Section 3 of the Act. Products that might fit either the definition of a food or a medicine are referred to a joint TGA/Food Standards Committee (External Preference Panel on Interim Matters) to make a recommendation as to whether it is more properly classified as a food or a medicine.

include medicines listed as having a higher level of risk and include all prescription and many non-prescription medicines.[186] Listed products are unscheduled medicines or other products that are usually available for self-selection and self-treatment by consumers, and/or those products considered to be of relative low risk.[187]

Complementary medicines (traditional, alternative or naturopathic substances) are usually listed products, although they may be registered depending on their ingredients and the claims made for them.[188]

The registration and evaluation process for registered drugs is complex and beyond the scope of this paper, suffice to state that sponsors must supply detailed evidence to substantiate any claims made about their products.[189]

Drug scheduling

In Australia access to drugs, poisons and medicines is governed by a scale of schedules that form part of the *Therapeutic Goods Act* and for the most part are adopted, gazetted or mirrored in state legislation. The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) contains the decisions of the National Drugs and Poisons Schedule Committee (NDPSC) whose task once a drug has been evaluated is to place the drug in the relevant schedule according to its level of toxicity, purpose of use, potency, danger it may pose to children, potential for abuse, need for the substance and the report or recommendations of the evaluator. The schedules generally specify who may sell or supply the drug, who may possess or administer it, the amount that may be supplied or the format in which it is presented. Access is progressively restricted 'where [the consumer's] general knowledge and the label information are not sufficient to overcome the consumer's lack of knowledge' (Galbally 2000b, p.18). The Standard is amended and consolidated annually, incorporating the decisions of the NDPSC, and is published four times a year. Figure 6.3 gives an annotated summary of the relevant schedules.

186 Those classified as Schedule 4 or 8 (high risk) or Schedules 2 or 3 (lower risk pharmacy products) on the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) (see below).

187 Listed medicines are unscheduled. While they still need to be assessed by the TGA for quality and safety, the TGA relies on the information provided by their sponsors as to their efficacy rather than conducting individual trials on these products.

188 See Section 52F of the *Therapeutic Goods Act 1989* and Schedule 14 of the Therapeutic Goods Regulations 1990. A discussion of complementary and self-selected medicines is beyond the scope of this chapter. Self-selected and over-the-counter medicines are governed by the Australian Regulatory Guidelines for over-the counter-Medicines (ARGOM) administered by the TGA. A Complementary Medicines Evaluation Committee has also been established under the TGA. It is interesting to note, however, that Victoria is the only state that has an official schedule (Schedule 1) for traditional Chinese medicines. See *Drugs, Poisons and Controlled Substances Act 1981*.

189 For a discussion of the registration and evaluation process, see Hirshorn and Monk 2006, pp.659ff. Details of the process are also contained in the Australian Regulatory Guidelines for Prescription Medicines (ARGPM) available on the TGA website (www.tga.gov.au). Many of the forms, formats and processes used by the European Union to present and assess drug evaluation applications have also been adopted by the TGA.

Table 6.3: List of scheduled drugs adapted from the standard for the uniform scheduling of drugs and poisons

- ***Schedule 1*** [In Victoria only] Traditional Chinese medicines and substances to be administered by accredited practitioners.
- ***Schedule 2*** includes substances that are considered to be able to be used safely when available from a pharmacy where professional advice is available. These substances include analgesics (eg. paracetamol) and antifungal preparations.
- ***Schedule 3*** products require the supervision of a pharmacist in their supply to advise the consumer on their safe and effective use. Substances covered in *Schedule 3* include some medicines to relieve the symptoms of asthma and some antihistamines.
- ***Schedule 4*** products require the intervention of a doctor, veterinarian or other authorised prescriber to diagnose the condition and prescribe the most effective treatment for that patient. These products include medicines to treat conditions such as infections (antibiotics), heart disease and depression. Once prescribed, these medicines can only be obtained from a pharmacy.
- ***Schedule 5*** includes substances with a low potential for causing harm, the extent of which can be reduced through using appropriate packaging with simple warnings and safety directions on the label.
- ***Schedule 6*** contains substances with a moderate potential for causing harm, the extent of which can be reduced through distinctive packaging with strong warnings and safety directions on the label.
- ***Schedule 7*** includes substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling and use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession storage or use may apply.
- ***Schedule 8*** covers products where, in addition to the *Schedule 4* controls, further access restrictions are placed on the prescribing of large quantities, prescribing for long-term treatment or in treating drug addiction. These substances include narcotics (eg. morphine) and drugs to treat attention deficit disorder (eg. methylphenidate).
- ***Schedule 9*** includes substances that are generally designated as illegal substances that are subject to abuse; the use, possession and supply of which is prohibited.

Source: Adapted and modified from Galbally 2000a, pp.21–22.

The objectives of scheduling are to reduce the level of accidental or intentional poisonings through inappropriate access to the drugs, provide expert intervention so as to redress information asymmetry between consumers and the pharmaceutical industry and provide a system whereby the diversion of medicines for inappropriate, unsafe or criminal use are minimised.[190]

The number of schedules signifies increasingly stricter controls. Each evaluated drug is assessed according to the factors of the various schedules in a 'cascading principle' whereby a drug is first assessed against the criteria in a higher schedule and if insufficient of these factors are pertinent it is assessed against a lower schedule and so on (TGA 2005a, p.4). The schedules are divided into those pertaining to medicines (Schedules 2, 3, 4 and 8), those relating to poisons (Schedules 5, 6 and 7) and Schedule 9, which covers prohibited substances. With regard to medicines, there are five major levels of access:[191]

190 A classic example is the rescheduling of larger packs of the drug pseudoephedrine from Schedule 2 to Schedule 4 as a measure to reduce the drug being diverted into illicit amphetamines. Despite directions from state Pharmacy Boards, some pharmacists were inadequately exercising appropriate professional standards by continuing to keep the drug on open display facilitating theft and diversion. By moving the drug into the higher schedule it became mandatory to have the drug removed from open display. For a discussion of this issue see the Drugs and Crime Prevention Committee, *Final Report*, Inquiry into Amphetamine and 'Party Drug' Use in Victoria (2004).

191 As indicated, Schedule 5, 6 and 7 concern household and industrial poisons and as such are not relevant in the context of this Inquiry. Schedule 9 contains controlled substances such as heroin that are available only for approved clinical or research purposes.

- **No schedule** – Open access or self-selection by consumers through supermarkets, pharmacies or health food stores.[192]
- **Schedule 2 (S2**) – Supply restricted to pharmacies (but personal supervision of a pharmacist in the sale not necessary).[193]
- **Schedule 3 (S3) –** Supply restricted to sale being supervised by qualified pharmacist.[194]
- **Schedule 4 (S4) –** Supply only with prescription by a medical professional (doctor or where relevant dentist, optometrist or veterinarian).
- **Schedule 8 (S8)** – Supply only with prescription *and* subject to other controls such as prior approval or grant of permit by government agency and/or restriction on repeats. Such a permit, for example, may be required for drugs such as morphine, methadone or the stimulant methylphenidate (Ritalin). This schedule recognises that whilst these drugs have legitimate therapeutic uses, they also have potential for abuse and/or addiction.[195] In some circumstances Schedule 8 drugs may only be prescribed by certain medical specialists (such as an oncologist).

For the purposes of this Inquiry, Schedules 4 and 8 are of the most relevance.

The rationale behind prescription only schedules (Schedules 4 and 8) is to ensure that:

- The condition from which the consumer is suffering is diagnosed correctly;
- The most appropriate treatment is prescribed; and
- The consumer has sufficient information and understanding necessary to enable him or her to use the medicine safely and effectively (Galbally 2000a, p.27).

Schedule 8 drugs in particular can be highly toxic when used inappropriately, are generally prescribed for serious and often terminal illnesses such as cancer, and have a very high potential for being abused or causing dependence.

192 Some of the factors to be taken into account in deciding a medicine does not need to be scheduled include: that it is for the use of minor ailments that can be diagnosed or managed by the consumer; the safe use of the medicine is well established; the risk profile of the medicine is low and well defined; and the medicine is unlikely to produce dependency (see TGA 2005a).

193 In some circumstances, usually in rural and remote communities where there is no pharmacist in close proximity, Schedule 2 poisons may be supplied by a poisons licence holder. See DPCSA Division 8. The Galbally Review discussed whether Schedules 2 and 3 should be merged into one single schedule for over-the-counter medicines, but ultimately decided against recommending this, subject to ongoing monitoring of the current system.

194 The idea being that the pharmacist will give professional advice on the administration of the medicine. See discussion below.

195 In Victoria this is done by the Drugs and Poisons Unit of the Victorian DHS, see discussion below. 'Pre-authorisation' also is required from Medicare Australia for medical professionals to prescribe Schedule 8 drugs in excess of the PBS quantity or repeat levels.

The SUSDP also contain appendices that supplement the schedules by establishing additional controls for certain drugs.[196] These may include controls with regard to storage,[197] handling, transport, recording, packaging, first aid, safety directions, advertising and labelling or to whom and under what conditions they may be sold.[198]

Products that are already scheduled may also be rescheduled on application from state health authorities, requests from industry or professional associations, a reference from the TGA or self-initiated by the NDPSC. Rescheduling usually occurs when there is a need for maintaining consistency with comparable products under a different schedule or there has been a perception that the risk profile of the product has either been increased or decreased (thus necessitating a move to a higher or lower schedule).[199] The Galbally Review noted that in recent years there has been a marked trend for devolution of prescription medicines to lower levels of control, thus increasing consumer access:

> This has seen a number of medicines move from Schedule 4 to Schedule 2 or Schedule 3, but rather fewer go to open sale, thus not significantly changing the number of OTC medicines available to the open market (Galbally 2000b, pp.46–47).

Licensing

In addition to the scheduling process, the other major regulatory safeguard to ensure the safety and efficacy of drugs and medicines in Australia is through the licensing system. The *Therapeutic Goods Act 1989*, its regulations and Customs laws make provision for the issuing, renewal, suspension and revocation of licenses for drug manufacture, importation, export and wholesaling. While the licensing schemes under the Act:

> do not provide any numerical restrictions on who can participate in the market, they do require operators to have specific knowledge, skills and character to deal with medicines and poisons safely and effectively. They aim to prevent

196 Appendix D for example places stringent restrictions on the administration of S8 drugs.

197 As would be expected the drugs and medicines in the higher schedules, particularly Schedule 4 and 8 drugs that can be diverted for illicit use, have more rigorous requirements with regard to their storage, display and record keeping provisions. See Therapeutic Goods Regulations 1990 and Drugs, Poisons and Controlled Substances Regulations 2006. For some controlled substances, particularly narcotics, stringent record keeping provisions must be observed pursuant to Australia's obligations under international drug treaties. For example, the *Narcotic Drugs Act 1975* requires records to be maintained and reports sent to the International Narcotics Control Board on narcotic drugs consumption.

198 The extent to which the states adopt the appendices is variable. This area is where there is probably the least uniformity. For example, in some states company representatives are not permitted to carry pharmaceutical samples for prospective supply, in other states they may do so if licensed. Provisions with regard to storage and display of S2 drugs also vary from state to state.

199 Drugs that have apparently resulted in adverse conditions or reactions post-marketing and scheduling are investigated or monitored by the Adverse Drug Reactions Committee (ADRAC), a subcommittee of the TGA.

> traders, without these attributes, gaining access to the market or, in some cases, provide for removing 'problem traders' from the market (Galbally 2000a, p.15).

For the most part the licensing system and associated safeguards, including strong codes of practice promoted by industry,[200] stringent quality control and assurance systems with which manufacturers must comply,[201] and a comprehensive system for inspections of manufacturers and distributors premises by TGA officers,[202] are viewed as ensuring best practice in drugs and medicines control in Australia. There have been few cases, for example, of rogue unlicensed persons engaging in the pharmaceutical trade in Australia (WHO 2002, p.63).[203]

Given these benefits associated with licensing, the Galbally Review was of the view that while the licensing system does act in restraint of trade in the sense that it restricts those who may enter and operate in the market, the overall benefits in terms of protecting public health and safety justify the restrictions, which should be maintained.[204]

Advertising

The *Therapeutic Goods Act* and associated state legislation basically prohibits the advertising of Schedule 4 (prescription), Schedule 8 (controlled substances) and some Schedule 3 (sales supervised by pharmacist) medicines. Such controls are directed towards the consumer. Where advertising is permitted, as is the case with some Schedule 2 and 3 medicines, the Therapeutic Goods Advertising Code[205] governs the acceptability and monitoring of such advertisements.

The rationale for the prohibition on advertising to consumers was explained in the Final Report of the Galbally Review:

> The underlying objectives of the restrictions on advertising relate to concerns that consumers – and particularly those in vulnerable positions because of serious health conditions – would not be in a position to assess the sort of claims that might be expected to appear in advertisements for many scheduled medicines (Galbally 2000a, p.50).

For the most part, advertising or promotion of drugs and medicines to qualified health care professionals is permitted, whether this is in medical journals, trade

200 See for example the Code of Practice of *Medicines Australia* at www.medicinesaustralia.com.au

201 See Section 36 *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990 (Part 4).

202 See Section 48 *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990.

203 For example, the WHO Review of comparative drug regulation systems found that the percentage of violations against Good Manufacturing Practice (GMP) standards in medicine manufacturing plants varied from 1 per cent in Australia to 60 per cent in Uganda and an extraordinary 83 per cent in Estonia (WHO 2002, p.73).

204 Although the Galbally Review did recognise there may be some justification in abolishing or at least liberalising some of the restrictions associated with drug licensing for drugs and poisons placed in the lower risk schedules

205 See Part 2 and Part 6 (Division 2) of the Therapeutic Goods Regulations 1990. The most recent version of the Code was tabled in July 2006 and can be accessed at the TGA website – www.tga.gov.au

magazines or by pharmaceutical company representatives. The advertising of such products to medical professionals and the use of sales representatives to promote and give doctors free products (sampling)[206] is also governed by the provisions of the Medicines Australia Code of Conduct, to which most pharmaceutical companies operating in Australia are signatories. A criticism has been made, however, that while Medicines Australia does a good job of reviewing inappropriate marketing and imposes hefty fines on its members who may transgress the Code, such actions always take place after the event (Health Report 2006).

The Galbally Review examined alternatives to the prohibitions on advertising of pharmaceutical products such as reliance on generic trade practices or consumer protection legislation. Again, it was felt that as this legislation is applied 'post-market' the damage might be done before any corrective action is taken (2000a, p.53). Therefore, apart from some relatively minor exceptions,[207] the Review did not support a relaxation of advertising restrictions.

Accessing drugs on the Internet

One issue pertaining to both advertising of and access to drugs and medicines that has raised concerns in recent years is the use of the Internet and e-commerce. While the current advertising restrictions of the *Therapeutic Goods Act* and its associated regulations and codes apply to all advertising, including the Internet, that is broadcast or otherwise disseminated in Australia, neither the Commonwealth or state governments have a great capacity to regulate 'spam' advertising that originates overseas. Unfettered access to drugs and medicines over the Internet poses dangers on two main levels. First, there may be doubts as to the purity and safety of the drugs in question. Second, even if the drugs are therapeutically 'safe', without the intervention of a qualified third party such as a doctor or pharmacist to advise on their usage consumers may either wilfully or through ignorance take these medicines incorrectly and unsafely. As the Galbally Review noted: 'This is an international problem and one which the Commonwealth Government and the governments of other countries are attempting to resolve' (Galbally 2000a, p.50).[208]

A related issue is that of Internet prescriptions. While the use of mail order or Internet prescriptions and delivery of medicines may be advantageous for

206 For a discussion of issues surrounding the practice of sampling, see Galbally 2000b, pp.94ff. This is one of the areas where state laws may differ. In Victoria, for example, pharmaceutical company representatives are not permitted to carry sample products when they meet on promotional visits with health care professionals. In some other states this may be permitted. The Review recommended that the regulation of sampling be removed from state jurisdiction and become subject to a national Code of Conduct administered by the Australian Pharmaceutical Manufactures Association (now Medicines Australia) (see Galbally 2000a, pp.xixff).

207 For a discussion of these exceptions, see Galbally 2000a, pp.65ff. The Review recommended that advertising regulation become the sole province of the Commonwealth. This would, however, require complementary state legislation in cases where the advertising is purely intra state (for example by a sole trading pharmacist). For a more general discussion of the regulation of pharmaceutical advertising see Hirshorn and Monk 2006, pp.682ff.

208 See also the discussion in Chapter 5.

consumers in remote and rural parts of Australia where medical practices and pharmacists are sparsely located, concerns have been expressed that these methods of supply are deficient because the face-to-face counselling of the doctor or pharmacist is not provided, a key aspect of addressing the information asymmetry between provider and consumer. Interestingly, however, consumer groups in submissions to the Galbally Review supported the use of mail order and Internet 'pharmacy' for the cheaper costs they provided. This was also one of the reasons that pharmacy groups were opposed to their proliferation (see Galbally 2000b). Pharmacists are also concerned about the dangers of 'medical misadventure' associated with laypeople buying medicines via the Internet. In a submission to this Inquiry the Pharmacy Board of Victoria expressed their concern that the 'public is not given sufficient awareness of the dangers of buying medicines online'. While the Board considers the TGA website to contain a good alert system with regard to online 'spam' advertising of medicines, few people would be aware of this service.[209]

The development of e-commerce in this and other fields certainly poses challenges and risks for consumers of pharmaceutical medicines. This is an area that is primarily the responsibility of the Commonwealth government. Nonetheless, it is also one that requires more consideration at state level should this Committee or another forum consider the issues this Inquiry has raised in the future.

The Galbally Review

The National Competition Policy *Review of Drugs, Poisons and Controlled Substances Legislation* (the Galbally Review) was conducted in 2000 and examined the restrictions on medicines and poisons supply imposed in national and state/territory legislation. The major issues it examined related to impositions on who can develop and supply drugs and medicines (particularly through scheduling, prescribing and licensing) and restrictions on how the goods can be supplied.[210] The ultimate object of the Review was to assess whether the benefits of the controls to the community as a whole outweighed the costs imposed on certain sectors (such as producers). The Review considered a number of alternatives to regulatory control including self-regulation, co-regulation particularly in association with professional standards developed by health professionals and codes of practice with industry groups, better education and training, and generic regulation through placing more reliance on general legislation such as consumer protection Acts[211] (Galbally 2000a). On balance the Review decided that the benefits of maintaining regulation did indeed outweigh any associated costs and for the most part should remain. Certainly the Review believed that the major features of the

209 See 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 2006.

210 A detailed discussion of the Review is beyond the scope of this chapter. For the Review's Terms of Reference, see Appendix A1 in Galbally 2000a, pp.103ff.

211 It was thought relying on consumer protection legislation was an inadequate safeguard, as usually such laws operate only 'after the event' (Galbally 2000b, p.128).

regulation system such as licensing and scheduling should remain.[212] The Galbally Review's *Final Report* and the response of the Australian Health Ministers' Advisory Council to its recommendations was unanimously approved by the Council of Australian Governments in June 2005. Currently, the transitional arrangements for a change to a new system are being undertaken.

One of the key concerns of the Review was that there is a need for greater uniformity of drug control and regulation across Australia. This concern was echoed in a later Report of the World Health Organization. Discussing countries with federal systems of government it stated that:

> Where drug regulatory responsibilities are divided, there is no unity of command over drug regulatory functions. The missing links resulting from fragmentation and delegation can undermine the overall effectiveness of regulation. Drug regulatory structures should be designed in such a way that there is a central co-ordinating body with overall responsibility and accountability for all aspects of drug regulation for the whole country (WHO 2002, p.3).[213]

The Galbally Review found that a lack of uniformity could result in the following jurisdictional problems:

- there are increased costs for business, of multiple standards required for labelling, storage, handling etc;
- the costs of establishing what the standards are in all the jurisdictions in which a company wishes to operate;
- there are inhibitions and problems for those health professionals moving across borders, especially for those practising near state borders;
- there are confusions and frustrations for consumers in a mobile society (associated with migration and travel) in identifying and using drugs and poisons safely and effectively; and
- there are costs for government of duplication of regulatory agencies in designing and monitoring standards and inefficiencies in administering those controls (Galbally 2000b, p.29).

212 The Review was prepared to deregulate some areas of therapeutic goods control, particularly in the area of advertising of drugs and medicines in the lower schedules. See the Review's Recommendations in Galbally 2000a, pp.xiv–xxiv.

213 One of the few weaknesses noted of the Australian regulatory system according to the WHO was that its federal system of government means that the TGA 'does not have the authority to assess and control the drug distribution system for the whole country' (WHO 2002, p.126).

Stakeholders and respondents to the Review, particularly from the pharmaceutical industry, argued that a lack of uniformity across the country increased the costs of compliance.[214] On the other hand, medical consultants indicated to the Review that a lack of uniformity could create problems in prescribing and dispensing for people taking medications in different jurisdictions (Galbally 2000b). This was a particular problem for those practising in border regions such as Albury–Wodonga.

To address the issues of uniformity the Review recommended that all the states adopt, where they have not already done so the provisions of the *Therapeutic Goods Act 1989* including scheduling decisions made under the SUSDP by reference into their state legislation. Eventually the Commonwealth will be working towards establishing uniform national model legislation in this area for adoption by states and territories.[215]

Other than problems associated with a lack of uniformity, which for the most part have now been resolved or are in the process of being changed,[216] it is generally agreed that the scheduling process and associated regulatory procedures work well in Australia. The problems lie, according to some commentators, not in the process per se but in the decisions that are made

214 Although happening relatively seldom, in some cases an over-the-counter medicine might be scheduled S2 in one state and S3 in another requiring separate labelling, packaging, different training programmes for pharmacists and their staff etc. Correspondence to this Inquiry by pharmaceutical company Mundipharma (August 2006) noted that pharmaceutical drug regulation should ideally be conducted on a purely national basis in Australia. It stated:

'Individual actions being taken by the various regulatory bodies – whilst all well considered and intentioned in isolation – demonstrate the fractured nature of the various approaches to these issues across Australia. Again, Mundipharma believes it is important to have, wherever possible, a nationally coordinated response to these matters in order to ensure ready access to S8 pain medication, whilst minimising opportunities for abuse and diversion. The power of a national approach, harnessing knowledge and expertise of all available stakeholders, to "get it right first time" should not be underestimated.

Frequent incremental changes to State and Federal legislation governing the control of S8 prescription products cause significant confusion amongst those health professionals required to abide by these controls, and consequent significant difficulty in complying. Whilst the laws may be good, lack of strict compliance by the various parties to the process weaken their effect and create opportunities for abuse and diversion of "controlled" prescription products.

Additionally, such a national response could address the important concern of a number of Australia's State Health Authorities of limited ability to detect and intervene in prescription drug abuse and diversion occurring across State borders.'

215 There was some resistance to this proposal during the Review consultation stage. The Australian Health Ministers' Working Party's response to the Review recommendations accepted this recommendation in principle but felt that further consultation is required (Australian Health Ministers Advisory Council 2003).

216 For a detailed account of how the recommendations of the Galbally Review will be put into practice, including a new proposed model for the scheduling of medicines, see TGA 2005a and TGA 2005b. The proposed new model has accepted one of the recommendations of the Review to divide the current scheduling committee into two. From late 2006 a Medicines Scheduling Committee (MSC) and a Poisons Scheduling Committee (PSC) will operate under a joint agency framework. The MSC will give advice on matters pertaining to Schedules 2, 3, 4, 8 (medicines) and 9 (prohibited substances). The PSC will give expert advice on poisons, household, agricultural and industrial chemicals (Schedules 5, 6, and 7). The content of the standard will in other respects remain essentially the same. Another recommended change to the system that has been accepted is the proposal to conduct the scheduling process at the same time, wherever possible, as the product evaluation/assessment rather than separately, as is currently the case. Such a change, it is argued, will result in great benefits in terms of time and cost savings. See generally Galbally 2000a.

under its provisions, for example whether a particular drug is marketed at the appropriate level of access. This issue is discussed further in Chapter 7.

Other concerns expressed with regard to Australia's system of drug regulation since the Galbally Review report was published include that insufficient attention is paid on occasion to post-marketing surveillance of drugs, the regulation of medical devices and the advertising of drugs and medicines. These are all important issues but beyond the scope of this Interim Report. The next major section of this chapter switches from a discussion of the macro levels of regulation largely administered through the Commonwealth to a closer examination of the oversight of drugs and medicines, prescribed, dispensed and administered at local level.

The regulation and administration of pharmaceutical drugs and medicines in Victoria

As the previous discussion indicates, the prescription and supply of medicines is somewhat a 'closed shop' that overrides the rules of competition policy, requiring as it does a qualified medical professional to mandate the possession of the drug and a qualified pharmacist to supply it. As such, a system of rules and guidelines has been developed at state level to ensure the best management of medicines and their administration in Victoria.

Legal control of drugs and medicines in Victoria

Most of the key features of the Commonwealth Therapeutic drugs legislation, at least as they relate to prescription medicines, have been incorporated into Victorian law. This has traditionally been done in a number of ways, outlined below.

The Therapeutic Goods (Victoria) Act 1994

First, the state *Therapeutic Goods (Victoria) Act 1994* (hereinafter TGVA 1994) implements, through mirror legislation, a system of therapeutic goods control complementary to those in the Commonwealth *Therapeutic Goods Act 1989*.[217] Thus, for example, Victorian sponsors and manufacturers[218] of therapeutic goods must comply with the listing and registration procedures of the Australian Register of Therapeutic Goods (ARTG) and with the applicable Commonwealth standards for the production or supply of the goods.[219] Evaluation of therapeutic goods applications in Victoria follows the same procedures as laid down at Commonwealth level[220] and the words and phrases

217 The Commonwealth Therapeutic Goods Regulations 1990 in turn recognises the *Therapeutic Goods (Victoria) Act 1994* (Vic) (TGVA) as the corresponding state law for the purposes of the federal act. See Section 3(1) *Therapeutic Goods Act 1989* (Cth) and Section 3 Therapeutic Goods Regulations 1990 (Cth).

218 TGVA 1994 Part 3.

219 TGVA 1994, Part 2.

220 TGVA 1994, Section 27. For example, as in the *Therapeutic Goods Act 1989*, the Victorian legislation includes the British Pharmacopoeia as the definitive standard reference with regard to the evaluation of drugs and medicines (see TGVA Section 67).

used in the Commonwealth Act are expressly adopted with the same meanings in the state legislation.[221]

The Poisons Code and List

The second major method by which the features of the Commonwealth regulatory system are incorporated into Victorian law is through the operation of the Poisons Code.

The Poisons Code operates subject to the provisions of Section 12 and 12A of the Drugs, Poisons and Controlled Substances Act (DPCSA). The Code includes a Poisons List and when adopted by the state Minister for Health incorporates any of the Commonwealth standards with regard to the advertising, labelling, storing or packaging of poisons and controlled substances.

The Poisons List in effect includes by reference Schedules 2–9 of the Commonwealth standard and an additional Schedule 1 pertaining to traditional Chinese medicines that is exclusive to Victoria. Provision is also made in the Victorian Act for any of the Commonwealth *Therapeutic Goods Act* appendices; any of the decisions or interpretations under the SUDSP; and any of the exemptions made under the Commonwealth standard or schedules to be incorporated by reference into the Victorian Poisons List. In effect this means that for most purposes the schedules and the drugs contained therein are the same at Commonwealth and state level.[222]

Victorian health law and practice also refers to 'drugs of dependence'. This term is used to describe all Schedule 8 drugs plus those Schedule 4 drugs that may be subject to abuse and illicit trading. Benzodiazepines are included as 'drugs of dependence'.[223]

Regulations made under the DPCSA also allow the Minister and where relevant the Secretary to the DHS Victoria (hereinafter the Secretary) to approve changes and make decisions that affect the operation of the Schedules and the drugs contained in the Poisons List. As the DPCSA regulations have only recently been significantly overhauled they will be discussed separately later in this section.[224]

Finally, the operation of the DPCSA is also subject to the advice of the Poisons Advisory Committee. This Committee, comprising of the Secretary and a

221 TGVA 1994, Section 4.

222 It remains to be seen whether this will change in the future. As discussed earlier in this chapter it may be that some time in the future Commonwealth law will cover the field if the states and territories cede their powers and a uniform national system based on federal legislation becomes a reality.

223 It should be noted that the Act and regulations discuss scheduled *poisons* (for example Schedule 8 poison). In the context of this chapter, however, the discussion more generally refers to scheduled *drugs,* to distinguish them from the more commonly understood reference to a poison (for example, household or industrial poison).

224 See Drugs, Poisons and Controlled Substances Regulations 2006. In particular, see Division One, Section 5 for a list of those persons deemed authorised to have Schedule 4, 8 and 9 drugs in their possession.

number of expert members,[225] advises inter alia the Minister on matters pertaining to the Poisons Code, Poisons List and issues with regard to the regulation and administration of drugs and poisons generally within Victoria.[226]

Licences, permits and warrants

Under the DPCSA a variety of licences, permits and warrants that are relevant to the regulation and administration of drugs and poisons (including prescription medicines) may be issued, refused renewed or revoked by the Secretary.[227] The licensing and permit system is the main way in which controls are maintained over the manufacture, sale and supply of scheduled drugs in the state. In conjunction with the regulations and the directives of the Secretary,[228] the licence system is applicable to manufacturers, wholesalers, retailers, medical practitioners, pharmacists and other health care professionals.[229]

The way in which a health professional such as a prescribing doctor operates in accordance with his or her licence is subject to a number of factors which include but are not restricted to his or her obligations under the Act, and also the regulations and any practice directions issued by the Drugs and Poisons Unit (DPU) of the DHS Victoria.[230] Equally important are any codes of practice, professional standards or guidelines issued by peak bodies or professional colleges such as the Medical Practitioners or Pharmacy Boards. The practice issues that arise from these obligations are discussed in more detail in Chapter 7.

Obligations and offences under the Act

Health professionals, particularly medical practitioners and specialist nurse practitioners, have a number of responsibilities under the Act to ensure

225 Including medical practitioners, pharmacologists, pharmacists and police representatives. See Section 15 DPCSA.

226 See Section 17 DPSCA for the functions of the Committee.

227 See generally DPSCA Division Four.

228 For example, under Regulation 6 of the Drugs, Poisons and Controlled Substances Regulations 2006, the Secretary has the power to approve the authorisation of certain scheduled drugs (including Schedule 4, 8 and 9 poisons) to certain classes of people. Recently the Secretary has authorised general approval for: registered optometrists to possess and administer a variety of Schedule 4 drugs including anaesthetics; qualified Australian ski patrollers to possess and administer certain Schedule 4 drugs in emergency situations; and hospital midwives to possess and administer single doses of pethidine or morphine to women in labour. For details of these and other approvals, see DHS Victoria 2006f, *Approved by the Secretary*, circular, located at DHS Victoria (Drugs and Poisons Unit), website – www.health.vic.gov.au /dpu/approve.htm (Accessed 3 July 2006).

229 See Section 20 DPCSA. Under this section, for example, a licence holder may manufacture and sell or supply by wholesaler any Schedule 8 or 9 drug, with the specific exception of heroin. The granting of permits to medical practitioners or nurse practitioners to prescribe drugs of dependence (Schedule 8 and in some cases Schedule 9) is specifically located in Section 34 of the Act.

230 Such guidelines or directives are issued regularly and are available online at www.health.vic.gov.au/dpu. The DPU is at pains to remind practitioners that as regulations and directives are amended regularly such guidelines must be thought of as 'dynamic'. See for example, *Guide to the Drugs, Poisons and Controlled Substances Regulations* 2006a, DHS Victoria, Melbourne.

prescription drugs are only prescribed, administered or dispensed to those people whose medical conditions warrant it.

The types of obligations that are incurred by practitioners generally relate to both their general ability to prescribe, dispense or administer medicines by virtue of their status as qualified and registered medical professionals or because of the permits or licences they have been given to prescribe or administer particular drugs, such as drugs of dependence, under the Act.[231] For example, provisions that may curtail the otherwise 'free hand' doctors and nurses have in conducting their professional responsibilities may include:

- Restrictions on to whom certain drugs may be prescribed[232]
- Restrictions on the period for which certain drugs may be prescribed[233]
- Special notification procedures with regard to people considered drug dependent[234]
- Conditions pertaining to the quantity (including repeats) or type of drug permitted to be administered or prescribed[235]
- Conditions pertaining to the reasons a patient may seek certain drugs.[236]

It is an offence for registered medical practitioners to administer, supply or prescribe Schedule 8 and 9 drugs and for nursing practitioners to administer Schedule 8 drugs without the authorised permits, although some exceptions are made for patients with malignant cancers for whom the prescription of opioid

231 See Section 34 DPCSA.

232 For example, under Section 34 permits may be issued for practitioners to prescribe Schedule 8 and 9 drugs to drug-dependent persons or non drug-dependent persons (for example to relieve the pain of terminally ill patients). Different conditions will apply in both cases. While most benzodiazepines do not fall within the permit category, a submission from the Transport Accident Commission (TAC) Medical Panel recommends that consideration should be given to make the prescription for long-term use of benzodiazepines subject to licensing or permit controls (Submission of TAC to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006).

233 For example, special permits may need to prescribe or administer a Schedule 8 or 9 drug to a non drug-dependent person for a continuous period greater than eight weeks.

234 Under Section 33 of the DPCSA, registered medical and nurse practitioners must give notice to the Secretary of any of their patients whom they consider to be 'drug dependent'. They must also give notice to the Secretary of their intention to prescribe, supply or administer Schedule 8 and 9 drugs (in the case of a medical practitioner) and Schedule 8 drugs (in the case of a nurse practitioner) for a period longer than eight weeks.

It has been argued that such notification requirements may act as a barrier to treatment for drug dependent clients. For a discussion as to why this may be the case, see Chapter 9.

235 As indicated in the earlier part of this chapter, such prescribing practices or conditions are also circumscribed by Commonwealth laws and policies. For example, medical practitioners must contact Medicare Australia for authorities to prescribe Schedule 8 drugs when the prescription quantity and/or number of repeats are in excess of the PBS maximum. This is *in addition* to any permit required by the state DPU. According to some commentators, 'obtaining authorisation is not well received by doctors and is seen as bureaucratic and not evidence based' (Liaw et al. in Duckett 2004, p.56).

236 For example a practitioner may only prescribe or administer drugs of dependence to a drug-dependent patient to assist with the clinical treatment of his or her condition rather than solely to support that drug dependence.

analgesics (Schedule 8 drugs) is appropriate.[237] It is also an offence for such practitioners to prescribe these drugs in excess of any quantities specified in the permits or for a period longer than the permit specifies.[238]

The Act and the regulations give some leeway to practitioners in observing these obligations. For example, there may be emergency circumstances or exigencies of clinical practice that prevent a practitioner from renewing or applying for a permit to administer drugs of dependence. In such situations it may be possible to give the required notice as soon as practicable after the prescription or administration of the drug.[239]

Nonetheless, contraventions of the Act are viewed seriously. Apart from any penalties issued under the Act or regulations, medical professionals are also subject to disciplinary proceedings from the various state professional boards.

Pharmacists also have specified obligations under the Act in addition to any professional codes of practice or guidelines they must observe. In particular, under Section 36 of the DPCSA a pharmacist who 'is called upon to dispense for any person greater quantities of or more frequently than appears to be

237 While this is the general obligation under state law, it cannot be divorced from the additional and supplementary requirements that bind a doctor under relevant professional guidelines. A good example is with the prescription of drugs of dependence. Assuming a doctor has the required permit to prescribe a Schedule 8 drug, he or she must also follow Medical Practitioners Board of Victoria guidelines that state:

'Whenever possible, doctors must attempt to authenticate the histories and documents presented by contacting the doctor, clinic or hospital cited by the patient.

A doctor must not administer or prescribe a drug of dependence to or for any person unless:

- that drug is for the medical treatment of a person under his or her care; and
- he or she has taken all reasonable steps to ascertain the identity of that person; and
- he or she has taken all reasonable steps to ensure a therapeutic need exists for that drug.

When a doctor does not have access to the patient's history, to comply with these requirements he/she would need to:

- be satisfied that the need is genuine by history and physical examination;
- be satisfied that there are no signs suggestive of drug dependence such as pupillary size or injection marks; and
- attempt to independently verify details of the history given by the patient for his or her need for drugs of dependence directly with the purported previous prescribers. (Medical Practitioners Board of Victoria, Circular: Drugs, Poisons and Controlled Substances Act 1981. Accessed 6 June 2006 at: www.medicalboardvic.org.au/content.php?sec=44).

This directive also has a comprehensive discussion of the other exceptional circumstances in which permits may not be required in clinical practice. Many of these cases concern the administration of Schedule 8 drugs to children (with Attention Deficit Disorders), the prescriber is an accredited specialist, and/or the prescription/administration takes place in hospital-based settings. Nonetheless, although permits may not be required, even in such cases the DPU will still need to be notified of the treatment regime.

238 See Section 35 DPCSA. It is of great concern that a submission to this Inquiry by the Victorian TAC states that 51 per cent of doctors prescribing for TAC clients prescribed Schedule 8 drugs without the relevant permits (Submission of TAC to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006).

239 For examples of how these emergency services may work in practice, see transcript of Evidence given by Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 13 July 2006.

reasonably necessary' any drug of dependence or drugs from Schedules 4, 8 or 9 is required to notify the Secretary of that fact.[240]

The above account is not exclusive of the offence provisions that are applicable under the DPCSA. They are the main ones, however, that relate to those who prescribe or administer the drugs rather than those who seek to abuse them. Other more general criminal law offences such as theft or trafficking are dealt with in the final section of this chapter.[241]

An overhaul of the system: The Drugs, Poisons and Controlled Substances Regulations 2006

While the DPCSA 1981 provides the broad framework for medicines, drugs and poisons control in the state, it is the regulations that govern the day-to-day practice issues that arise with regard to inter alia the prescription, dispensation and administration of scheduled drugs and medicines. These regulations have been recently amended partly in recognition of the complexity of the issues associated with the prescription and dispensation of these medicines.

240 Of course the legal obligations imposed upon medical practitioners, nurses and pharmacists can and are compromised by the vicissitudes of practice. This may be because of ignorance, wilful neglect, the constraints of medical practice (for example, short consultation periods that do not allow a doctor to explore options other than pharmaceutical prescription), or even criminal behaviour. Some coronial cases, for example, relate incidences of doctors who did not apply for or receive permits to prescribe scheduled drugs, prescription anomalies or other failures to follow regulations or appropriate procedures. For example, see State Coroner Victoria, Case No: 1720/99 (1 March 2001) where methadone was allegedly prescribed and dispensed for the deceased, already taking benzodiazepines, without the appropriate permit.

At the extreme end of such cases is the criminal behaviour of professionals who abuse the system with malevolent intent. The most notorious case in recent years being the murderous acts of Dr Harold Shipman in England. See www.the-shipman-inquiry.org.uk

Following the regulations appropriately also assumes a culture in which health professionals are encouraged and supported to follow the system. For example, the obligation of pharmacists to report suspicious or inappropriate requests for dispensation under Section 36 DPCSA assumes that the pharmacist will feel confident to question the prescribing patterns of their professional colleagues in medicine. This may not always be the case.

For a discussion of the relationship between pharmacists and prescribers and the possible problems that may arise when pharmacists believe there has been inappropriate or excessive prescribing of medicines, see Transcripts of Evidence of the Pharmaceutical Society of Australia (Victoria) (Mr John Ilott and Mr Irvine Newton) and the Pharmacy Guild of Australia (Victoria) (Mr Dipak Sanghvi and Mr Maurice Sheehan), Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearings, Melbourne, 19 June 2006.

241 It is axiomatic that health professionals who abuse or misuse drugs of dependence and certain other scheduled drugs without due cause or authorisation may be subject to criminal penalties and/or action for professional misconduct. A submission to this Inquiry by the Nurses Board of Victoria (NBV) states that in 2004–2005 a total of 23 complaints were made to the NBV with regard to the abuse of medications by nurses, including the misappropriation of medications from the workplace:

'However, these complaints must be considered within the context of a lack of a legislative framework that requires mandatory reporting. The Board is aware that not all incidents are reported to the Board, including some situations where the employer chooses to manage the incident within the employment relationship' (Submission of the Nurses 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, July 2006).

For a more general discussion of the issue of health professionals who abuse drugs and medicines, including benzodiazepines, see Chapter 5.

The issue of criminal charges and penalties for drug possession and trafficking is considered later in this chapter.

The new regulations cover a wide variety of matters pertaining to the prescription, dispensation and administration of prescription and other drugs and poisons.[242] They include:

- New criteria for computer generated prescriptions[243]
- An extended range of persons who may be able to possess or administer scheduled drugs and medicines in certain circumstances[244]
- Stricter rules on ascertaining the identity of patients seeking drugs of dependence[245]
- Stricter rules on the notification of fraudulent obtaining of drugs of dependence[246]
- More stringent requirements for the storage and record keeping of Schedule 4 and 8 drugs.

Of particular relevance in the context of this Inquiry are the tighter controls imposed on the dispensation of Schedule 4 and 8 drugs (including benzodiazepines) by pharmacists. Pharmacists in most circumstances must only supply such drugs on the presentation of an original prescription[247] from an authorised person such as a medical practitioner (or where relevant, nurse practitioner, dentist, optometrist etc).[248] However, in certain defined emergency circumstances a pharmacist may supply a Schedule 4 drug (which would include most benzodiazepines) without a prescription where the pharmacist is satisfied that there is an immediate therapeutic need for the drug.[249] It should also be noted that a pharmacist must not supply a Schedule 8 drug to a patient on the prescription of a medical practitioner unless that practitioner is registered in Victoria.[250]

The above account of the 2006 changes to the law governing drugs and poisons administration in Victoria is a relatively rudimentary framework that

242 Unless otherwise specified the regulations discussed in this section primarily apply to Schedule 4 and Schedule 8 drugs only.

243 See Section 26 DPCS Regulations 2006.

244 For example, in defined circumstances ambulance officers may be able to administer certain Schedule 4 and 8 drugs or a municipal council officer employed in environmental health may administer Schedule 4 vaccinations as part of an authorised immunisation programme. See Table in Division One, Section 5 DPCS Regulations 2006 for a full listing of all authorised persons or class of persons.

245 For example, unless the patient is in effect well known to the health care professional (including doctors, nurses, pharmacists and dentists), he or she must not prescribe, sell or supply a drug of dependence to that person unless 'all reasonable steps' have been taken to ascertain the identity of the person and all reasonable steps have been established to ensure a therapeutic need exists for the drug. See DPCS Regulations 2006, Division 2.

246 Health care professionals who suspect that a person has obtained drugs of dependence or prescriptions for them by fraud or false pretences are required to notify both the Victoria Police and the Secretary of the DHS (DPCS Regulations 2006, Regulation 14).

247 Under Regulation 16 there are defined circumstances when a pharmacist may supply a Schedule 4 or 8 drug on a copy of the original prescription.

248 See Regulations 15–17 DPCS Regulations 2006 for further details of the obligations and requirements with regard to pharmacists in these circumstances.

249 See Regulation 15(2) DPCS Regulations 2006.

250 See Regulation 17, DPCS Regulations 2006.

outlines the most salient points applicable to this Inquiry. The devil, however, is in the detail. The regulations need to be read carefully and in conjunction with the various practice directions of the Drugs and Poisons Unit of DHS Victoria.[251] In addition to the advisory statements issued by the professional colleges and peak bodies. Chapter 7 will also examine the problems associated with the prescribing and dispensation of these drugs in light of the regulatory framework discussed here.

The final part of this chapter, however, examines other legal aspects pertaining to the use and misuse of prescription and other pharmaceutical drugs. Rather than focusing on the regulation of these drugs per se, the discussion looks at the offences that apply when these regulations and laws are infringed.

Criminal laws pertaining to the abuse of prescription and other pharmaceutical drugs

The final section of this chapter examines the criminal and offence provisions that apply when otherwise licit drugs such as benzodiazepines are used illicitly. The first part of the section examines those specific offences that pertain to the use of prescription drugs under the DPCSA. The second part examines more generally the criminal law provisions with regard to illegal possession, manufacture and trafficking of drugs of dependence, including but not restricted to prescription and pharmaceutical drugs such as benzodiazepines and opioid analgesics.[252] The final part examines relatively recent changes to the law that apply where the use of prescription drugs has adversely affected the driving of a person in charge of a motor vehicle.

Prescription drug offences

While prescription drugs are included in the general drug laws that apply to possession and trafficking, there are also some criminal offences that apply specifically to these drugs because they are only available when prescribed by a qualified medical practitioner or supplied by a qualified pharmacist. The two major offence types are forgery of prescriptions or knowingly presenting forged prescriptions in order to illegitimately obtain drugs, and obtaining drugs through fraud or false pretences. Offences of forgery of prescriptions are found in Section

251 Particularly circulars such as *Key Prescribing Requirements for Medical Practitioners Practice* (DHS Victoria 2006b); *Obtaining Information about Drug Seeking Patients* (DHS Victoria 2006c); *Managing Drugs in General Practice* (DHS Victoria 2006g); and *Interventions by Pharmacists* (DHS Victoria 2006h). All available at http://www.health.vic.gov.au/dpu/

252 An issue of great importance in this respect is the diversion of pharmaceutical drugs such as pseudoephedrine and precursor chemicals to manufacture amphetamines such as 'speed'. However, as this Committee has comprehensively canvassed the issues pertaining to this practice in its Inquiry into Amphetamine and 'Party Drug' Use, it will not revisit this issue in this Interim Report other than to state that since that Inquiry was conducted large packs of pseudoephedrine based pharmaceuticals have been rescheduled to Schedule 4 (Prescription only medicine). The interested reader is also referred to the *Final Report* of that Inquiry for further details of pseudoephedrine diversion and amphetamine manufacture. See also the Drugs, Poisons and Controlled Substances Bill 2006 for recent proposed changes to the laws relating to amphetamine and designer drug manufacture from precursor chemicals.

77 for drugs of dependence and Section 36A for other prescription drugs.[253] Obtaining drugs through fraud or false pretences provisions are found in Sections 78 (drugs of dependence) and 36B (other prescription drugs) of the DPCSA.[254] The major difference between the offences that apply to drugs of dependence (Sections 77 and 78) are that a person found in contravention of these offences is liable to a sentence of imprisonment whereas a fine only will apply to the offences that apply to other prescription drugs (Sections 36A and 36B).

One final point that should be made in the context of prescription offences relates to those people who 'fake' their symptoms when presenting to a doctor or other medical professional in order to illegitimately obtain a prescription for their drug of choice. The Turning Point Alcohol and Drug Centre have noted that:

> Symptoms have reportedly often been faked in order to obtain the drugs. Of those faking symptoms in Victoria, insomnia (57%), anxiety (42%) and opiate dependence (31%) were the most commonly reported symptoms used to obtain benzodiazepines and/or opioids (Victorian Department of Human Services 2002a).[255]

A submission from the Australian Medical Association (AMA) (Victoria) to this Inquiry has stated that, as behaviour such as the faking of medical symptoms is currently not subject to any legal consequences, 'The Committee [DCPC] might consider whether a civil or indeed a criminal penalty might act as a deterrent to this behaviour'.[256]

While this Committee does not dismiss such a suggestion out of hand, it would seem there may be myriad legal, ethical and practical problems in implementing such a law. The Committee believes further investigation is required before such a recommendation could be adopted.[257] In the meantime,

253 This area of the law is somewhat unclear and confusing. Section 36A is stated to apply to Schedule 8, 9 and 4 poisons that are *not* drugs of dependence. Section 77 covers all other cases (that is forgeries of prescriptions for drugs of dependence being drugs listed in DPCSA Schedule 11). While there are certainly drugs such as antibiotics that may fall within Schedule 4 and are not drugs of dependence, most Schedule 8 drugs are drugs of dependence and as such are included in Schedule 11 of the DPCSA which classifies drugs of dependence for the purposes of trafficking and criminal possession (see below). In effect this seems to make Section 36A largely superfluous, at least as it pertains to Schedule 8 and 9 poisons.

254 Similarly, while Section 36B is applicable to obtaining Schedule 4, 8 or 9 poisons through false representations or to cases where a person is in possession of such drugs without appropriate authority it is particularly stated not to apply to drugs of dependence. Again, as most if not all Schedule 8 and 9 drugs are drugs of dependence it is unclear as to how Section 36B applies in these circumstances.

255 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

256 Submission of the Australian Medical Association (Victoria) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

257 It may be that further investigation of this issue could be embarked upon should a supplementary Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria be undertaken in the 56th Parliament. See the Recommendation in Chapter 10 regarding a continuation of the Inquiry.

it may be that the AMA's alternative recommendation of providing 'a focus on patient education as to the harms of the misuse of prescription and over-the-counter pharmaceuticals' may be more suitable at this stage.

General laws pertaining to criminal possession and trafficking

While the criminal law as it relates to drugs is primarily the responsibility of the states and territories, it is to some degree influenced by international conventions and national laws.[258] Commonwealth criminal law pertaining to drugs, including prescription drugs (mainly opioid analgesics such as morphine, oxycodone etc), predominantly concerns the illegal import and export of drugs and particularly 'narcotic goods'. These provisions are found in Section 233B of the *Customs Act 1901* and its associated schedules.[259]

Victorian law

The Victorian DPCSA 1981 covers drug offences occurring within the jurisdictional boundaries of Victoria. These include offences pertaining to:

- Use
- Possession
- Cultivation[260]
- Trafficking.

Use

The use of a drug of dependence[261] other than cannabis provides for a maximum penalty of 5 penalty units or imprisonment of one year or both (Section 75(b) *Drugs, Poisons and Controlled Substances Act 1981*). The offence of using a drug of dependence in practice mainly applies to illicit drugs such as heroin rather than prescription drugs per se, although certainly opioid analgesics such as morphine can be used illicitly.

258 The most relevant treaties are:
- The United Nations Single Convention on Narcotic Drugs (1961);
- The United Nations Convention on Psychotropic Substances (1971); and
- The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988).

For a discussion of the international aspects of drug law and how these conventions have been incorporated into domestic law see Drugs and Crime Prevention Committee, Inquiry into Amphetamine and 'Party Drug' Use in Victoria *Final Report,* May 2004.

259 The drugs subject to criminal penalties for trafficking are found in Schedule 6. For further discussion of Commonwealth criminal law in this context, see Drugs and Crime Prevention Committee, Inquiry into Amphetamine and 'Party Drug' Use in Victoria *Final Report,* May 2004. See also Winford 2006 for a good general account of the law.

260 Cultivation is clearly irrelevant for the purposes of this chapter, relating as it does to predominantly cannabis.

261 For the purposes of these offences, drug of dependence is defined by reference to the drugs listed in Schedule 11 of the DPCSA 1981. This is not to be confused with the drug schedules that have been incorporated by reference into the Act from the Commonwealth standard. Thus a Schedule 8 drug such as morphine will also appear in Schedule 11 for the purposes of being a drug of dependence that can be the subject of criminal charges such as trafficking.

A variety of diversion programmes are available for people charged with non-violent drugs offences who can show that they have a 'drug problem'. These include the Court Referral and Evaluation for Drug Intervention and Treatment Program and Drug Treatment Orders under the new Drug Courts. A discussion of these programmes is beyond the scope of this Interim Report (for further information, see Winford 2006).

Possession

Possession is an indictable offence under Section 73 of the Act. Winford explains the relevant law as follows:

> Under common law, a person is in possession of a drug if he or she has physical control or custody of the drug to the exclusion of others not acting with the person. The prosecution must prove knowledge by the person of the presence of the drug and an intention by the person to possess the drug. In many cases, custody of a drug may supply sufficient evidence of possession, including the necessary mental element. This is because the inference of knowledge may often be drawn from the surrounding circumstances.
>
> As well as its common law meaning, possession has an extended meaning under the *Drugs, Poisons and Controlled Substances Act* 1981; section 5 states that a person is in possession of drugs if he or she is in possession of drugs that are:
>
> - On any land or premises occupied by the person; or
> - Used, enjoyed or controlled by the person in any place whatsoever, unless the person satisfies the court to the contrary (Winford 2006, p.119).

With the exception of cannabis, the penalties relating to possession of a drug that is not related to trafficking is $3,000 and/or one year's imprisonment or both (Section 73(1)(b)).

Trafficking

The law of trafficking is complex. In simple terms, if the prosecution proves the following matters:

- the accused was in possession
- of a drug listed in Schedule 11 of the DPCSA 1981
- of a quantity that is a *trafficable quantity*,

then this will be *prima facie* evidence of the crime of trafficking in the particular drug.

A trafficable amount is determined by reference to a prescribed weight listed for that drug in Schedule 11 of the DPCSA 1981. Under Section 70(1) of the Act, the definition of trafficking has been extended to include preparing or manufacturing a drug of dependence for trafficking, in addition to sale or possession for sale of the drug. Of particular importance is the fact that at state level the trafficable amount of the drug (in powder form) is no longer weighed

as pure amounts: 'The relevant weight is now the weight of the whole mixture, including substances other than the drug' (Winford 2006, p.122). Drugs that *are* weighed in pure amounts, which would include most prescription drugs, are listed in Part One of Schedule 11. A trafficable amount in methadone, for example, is listed as 2 grams pure weight. Trafficable amounts of diazepam and temazepam are 2 and 3 grams respectively.

In addition to trafficable quantities, a person may also be convicted of the more serious crime of trafficking in a *commercial quantity.* Commercial quantities and large commercial quantities for drugs of dependence are also found in Schedule 11 of the Act. The current commercial quantity of methadone, for example, is 2 kilograms (pure amount).

Trafficking offences of non-commercial amounts attract a maximum penalty of 15 years imprisonment. This sentence increases to 20 years imprisonment when the person is convicted of trafficking to a person under the age of 18.

A conviction for trafficking in a commercial quantity results in a maximum penalty of 25 years imprisonment. If the person is convicted of trafficking in a large commercial quantity, the penalties are even more severe – maxima of life imprisonment and in addition up to $500,000 fine.

Laws regarding theft and associated offences

Clearly, the criminal law provisions with regard to theft, burglary, robbery, fraud and associated offences will also be applicable where prescription drugs have been illegitimately obtained.[262] The circumstances where this may be relevant range from 'ram-raids' or break-ins on pharmacies to obtain drugs,[263] theft of prescription pads from medical surgeries or doctors' bags, or theft of medicines and drugs by people working in the health care field. Fraudulent means have also been used to obtain computer software to generate unauthorised prescriptions. Similarly, scanners have been used to obtain a genuine computer generated prescription upon which the patient details, drug, quantity and/or number of repeats may be fraudulently changed to receive unauthorised drugs.[264]

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262 Victorian criminal laws with regard to theft and associated offences are primarily found in the *Crimes Act 1958*. The major offences that are relevant in this context are Section 74 (Theft), Section 75 (Robbery), Section 75A (Armed Robbery), Section 76 (Burglary), Section 77 (Aggravated Burglary) and Section 81 (Obtaining Property by Deception).

263 A relatively common occurrence when temazepam liquid-filled capsule products were on the general list of the PBS. Since those products were taken off the market, the drugs most subject to theft and burglary are pseudoephedrine based products. See 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 2006.

264 See 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 2006.

Theoretically, a person could be charged under Section 83A of the *Crimes Act 1958* (Falsification of Documents) for such conduct, but it is more likely that they would be charged under the specific forgery of prescription provisions of the DPCSA outlined earlier in this chapter.

Drug driving and road trauma offences

A particular problem associated with prescription drugs is the harmful consequences that may follow from the effects of taking them on driving or being in control of a motor vehicle.[265] In a submission to this Inquiry, VicRoads stated that road trauma caused by drug-impaired driving is a worldwide problem and that all impairing drugs including prescription drugs have a 'dose related accident risk relationship'. In their submission Vicroads refer to a report published in 2003 by the United States Highway Traffic Safety Administration. This report:

> [r]eviewed the literature on the effects of a wide range of drugs on driving performance. The classes of drugs considered were narcotics, central nervous system (CNS) depressants, CNS stimulants, cannabis, antidepressants, antihistamines, and other drugs that have been investigated in a few individual studies.
>
> The report concluded that with respect to the acute effects of drugs, the following drug classes have a high potential for significant impairment of driving and driving-related performance: narcotics, long-life benzodiazepines in therapeutic doses, short-life benzodiazepines in high doses, barbiturates, 1st generation H1 antihistamines, and some antidepressants…[266]

In summary, Vicroads comments that this report and other research literature indicates that:

> [m]ost benzodiazepines can cause significant impairment of driving and driving-related tasks, especially at high dosages. However, it has been argued that therapeutic dosages create impairments that may be less hazardous to driving than the illnesses they are treating.[267]

Similarly, in a review of driving under the influence of drugs law in New South Wales, Godfrey and Phillips state that the five drug groups commonly seen in drug-impaired drivers are:

- Alcohol
- Cannabis
- Opiates and opiate derivatives
- Benzodiazepines; and
- Stimulants (2003, p.16).

Notwithstanding such concerns, it is only relatively recently that Australian legislatures have enacted laws and procedures that penalise motorists who drive

265 For a discussion of the particular harms and injuries associated with prescription drugs and driving, see Chapter 4.

266 Submission of VicRoads to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

267 Submission of VicRoads to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

with either any or a specified amount of illicit (and licit pharmaceutical) drugs in their system in ways comparable to driving under the influence of alcohol provisions (see Godfrey & Phillips 2003).

Currently in Victoria there are two major ways in which a person impaired with a drug other than or in addition to alcohol may be charged with a driving offence. These are described as follows.

Driving or being in charge of a motor vehicle while drug impaired[268]

This charge is used when a driver has one or more drugs in their system, the driver's behaviour consequent to a drug assessment test is consistent with 'drug related behaviour' and this behaviour could result in the driver being unable to drive properly.[269]

The *Road Safety (Amendment) Act 2000* specifies the procedure to identify impaired drivers and gives Victoria Police the power to take blood for suspected drug impairment cases.[270] Ordinarily, a police officer will have first tested a driver suspected of driving while impaired for blood alcohol levels by a standard breath test. If the blood alcohol reading is significant the driver will usually be charged with an alcohol-related offence. If no or low alcohol readings are obtained, police may continue to test the driver for drug impairment. VicRoads explains the procedure as follows:

> The basic steps involve a Roadside Opinion by Police, a Standard Impairment Assessment (SIA) by a trained assessor, a blood sample for confirmation, and expert evaluation of behavioural and toxicological evidence.
>
> The Standard Impairment Assessment is based on established psychomotor tests. If the Impairment Assessor concluded that the driver might be impaired due to drug use, the driver may be required to provide a blood sample for analysis for the presence of drugs.[271]

Drivers have a defence to this charge if they can establish that the drug in question was a legitimately prescribed drug. The relevant law states:

> If on an analysis carried out in accordance with this Part, no drug other than a permissible non-prescription drug or a prescription drug was found present in the person's body, it is a defence [to the charge]…for the person charged to prove that-
>
> (a) he or she did not know and could not reasonably have known that the permissible or the prescription drug, or the combination of those drugs, so found would impair driving if consumed or used in accordance with

268 (Section 49(1)(ba) *Road Safety Act 1986*.

269 (Section 49(3A) *Road Safety Act 1986*.

270 A person may be additionally charged in relevant circumstances for refusing to undergo a drug impairment assessment (Section 49(1)(ca)) and/or providing a blood or urine sample after a drug impairment assessment (Section 49(1)(ea)).

271 Submission of VicRoads to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

advice given to him or her by a registered medical practitioner, a dentist or a pharmacist in relation to the drug or combination of drugs; and

(b) he or she consumed or used that drug or combination of drugs in accordance with that advice.[272]

Convictions for driving while drug impaired carry a minimum licence disqualification of 12 months (first offence) or two years for a second or subsequent offence.

A submission from the Victoria Police to this Inquiry states that it generally believes the new laws and testing procedures for drug driving impairment under Section 49 of the *Road Safety Act* have resulted in positive outcomes. In particular, the testing procedures 'provide police with an effective mechanism to identify and remove high risk drivers from the road and a considerable increase in the awareness of drug driving as a significant road safety concern'.[273] Victoria Police also note that the procedures have been implemented without difficulty although there is a significant operational time commitment involved in both training officers with regard to the new specialised procedures and the time involved for the processing of suspected offending drivers.[274]

Overall, Victoria Police considers that:

> The legislation has proved to be extremely successful as a mechanism for police to identify and remove drug impaired drivers from the road. Of the 324 drivers prosecuted under the legislation to 30 June 2004 only 3 cases did not result in conviction. A further 35 drivers were detected and identified as being impaired for reasons other than [illegitimate] drug use (medical conditions) and were referred for administrative driver licence review.[275]

Road Safety (Drug Driving) Act 2003

In Victoria the *Road Safety (Drug Driving) Act 2003* has amended the parent *Road Safety Act* to include drugs, in addition to alcohol, for the purposes of random breath testing and the provision of drug driving infringement penalties.

The rationale behind such an enactment was clearly the dangers associated with drug driving and the increasing incidence of drug-related motor accidents in recent years.

Drug is now defined in the parent Act as:

272 Section 49 (3B) *Road Safety Act 1986*.

273 Correspondence from Victoria Police (Traffic Alcohol Section) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

274 Correspondence fromVictoria Police (Traffic Alcohol Section) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

275 Correspondence fromVictoria Police (Traffic Alcohol Section) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

> a substance that is a drug for the purposes of this Act by virtue of a declaration under sub-section (3) or any other substance (other than alcohol) which, when consumed or used by a person, deprives that person (temporarily or permanently) of any of his or her normal mental or physical faculties.[276]

While such a definition could encompass most prescription drugs, currently the use of random breath testing, however, solely applies to *prescribed illicit drugs*, which at this stage includes only cannabis and methamphetamine and certain 'party' or designer drugs such as MDMA ('ecstasy').[277]

Despite the current restricted class of drugs to which the legislation applies, VicRoads suggests that the technology can be utilised to make saliva testing for benzodiazepines a possibility:

> The manufacturers of the main first roadside drug test have indicated that their devices performance characteristics could be set to only provide a positive result for drivers who have high misuse/abuse levels of the drug. The device would not give positive results for drivers who follow the medical guidelines for prescription use of the drug.[278]

VicRoads intends to seek funding in the next business planning cycle (2007/2008) to assess the suitability of these devices. If the review indicates positive outcomes they will then put forward a proposal to extend the programme.[279]

Victoria Police is more equivocal in their support for random saliva testing to be extended to include certain pharmaceutical drugs. Unlike their support for targeted drug driving impairment referred to in the previous section, they believe that before moving towards an extended random drug testing regime a number of factors need further consideration. These include:

- There is a high level of legitimate benzodiazepine type drug use in the treatment of medical conditions. Consequently, a large number of drivers will be driving when using benzodiazepine type drugs for legitimate medical reasons.
- The relationship between drug dose, drug affect and the drug level present in the body is influenced by the physiological tolerance to the drug in an individual. Many factors play a role in what level of tolerance is present in an individual. Such factor include, the drug dose

276 Section 3 *Road Safety Act 1986*.

277 The initial legislation passed in 2003 established the oral fluid testing procedures on a trial basis only. The legislation was made permanent with the passing of the Road Safety (Drugs) Bill, which commenced on 10 May 2006.

278 Submission of VicRoads to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

279 Submission of VicRoads to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

administered, the frequency of drug administration and the time span over which the drug is administered.

- There is limited research information available in respect of what level of benzodiazepine type drug present in a person produces impairment of psychomotor skills to such an extent as to result in an inability to drive a motor vehicle safely.
- There is limited research information available to indicate what level of benzodiazepine type drug present in a person may be considered a therapeutic level as opposed to a level consistent with misuse and the presence of impairment.
- The currently available technology to test saliva for benzodiazepine type drugs in a roadside situation is relatively limited in terms of accuracy in respect of the level of drug present in a sample.[280]

In short, Victoria Police believe further research and investigation is required into the links between prescription drug use (particularly benzodiazepines) and the driving of motor vehicles and any dangers that may flow from this combination before such a new regime can be introduced.

Conclusion

Law and legal controls do not consist solely of the written law, regulations, offences or proscriptions. This is particularly true of an area as complex and sensitive as drug regulation where legal matters become entangled with medical and social issues to a large degree. Moreover, prescription and pharmaceutical drug misuse and abuse is particularly complicated by the fact that for the most part one is dealing with licit substances, although sometimes in illicit or illegitimate ways.

An essential aspect of the regulation of prescription drugs is to examine the ways in which these laws are administered or carried out in practice, in addition to discussing the guidelines and directives that health care professionals may be subject to in the performance of their duties. This and other matters pertaining to how regulation operates in practice is the topic of the next chapter.

The following is a list of issues pertaining to the regulation of pharmaceutical substances that may need to be considered in the ongoing work of the Drugs and Crime Prevention Committee with regard to the current Inquiry.

280 Correspondence from Victoria Police (Traffic Alcohol Section) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

Questions for further consideration

Whether (notwithstanding the recommendations of the Galbally Report), the current system of drug scheduling is efficient, workable, comprehensive and easy to implement.

What improvements can be made to the system to enable drugs to be scheduled and particularly rescheduled more speedily?

Even if the structures and procedures of drug scheduling are basically sound, are drugs in fact being placed in the most appropriate scheduled categories? Do the current guidelines and processes ensure that this occurs?

What systems can be put in place to prevent or at least reduce the amount of Internet spam with regard to the advertising and sale of prescription medicines? What can be done on an international/national and state level to address this?

What guidelines and procedures are available with regard to prescriptions issued on the Internet? Can these be improved upon?

7. Prescribing Benzodiazepines and Other Pharmaceuticals

Introduction

The previous chapter discussed the various laws and regulations that govern the availability and safe, effective prescribing of drugs that are the focus of this Inquiry. It is evident that the professional practices of those given authority to prescribe drugs and medicines, such as medical practitioners and dentists, are key factors that can have influence on prescription drug misuse. The role of pharmacists is also crucial in this regard.

Regulatory, government and professional organisations and agencies also play an important part in supervising or overseeing the prescribing and dispensation of medicines and drugs. For example, the Department of Human Services (DHS) provides direction and advice to professional boards and individual practitioners on the requirements of good prescribing practice. The police are also involved in detecting and responding to prescription forgery or monitoring the way in which the hazardous use of drugs may impair driving skills.

This chapter will discuss the various national and state organisations, policies and procedures in terms of their role in preventing and responding to pharmaceutical misuse. Similarly, the role of professional boards and bodies will be discussed, with particular reference to their responses to the risks of pharmaceutical misuse. The national and state policies and activities of the professional boards and bodies have contributed to the development of standards of practice, clinical guidelines, learning objectives and training programmes that aim to directly and indirectly prevent and effectively respond to pharmaceutical misuse. These will be briefly explored. Finally, compliance with standards of practice that ensures safe and effective prescribing is reliant on quality information and monitoring systems. The role of such systems will be discussed, with particular reference to needs in the Australian context.

The 'stewardship' of quality use of medicines

The procedures for best practice prescription and dispensation of medicines that are adopted by medical practitioners and pharmacists (or not, as the case

may be) are governed by a variety of bodies, policies, regulations and guidelines. These bodies and policies include those summarised in the following table:

Table 7.1: Key organisations, schemes and policies governing access to pharmaceuticals

Medicare Australia	Formerly referred to as the Health Insurance Commission (HIC) Medicare Australia is located in the Australian Government Department of Health and Ageing (DoHA). Medicare Australia is responsible for, among other things, Quality Use of Medicines (QUM), the Professional Services Review Scheme (PSR) and the Pharmaceutical Benefits Scheme (PBS).
The Department of Veterans Affairs (DVA)	The DVA has responsibilities related to the services (medical and pharmaceutical) provided to Veterans.
The Australian National Medicines Policy	This Policy guides the strategies to ensure access to safe and effective medications and prescribing and dispensing of these medications.
The Quality Use of Medicines (QUM)	QUM is a central component of the Australian National Medicines Policy. QUM identifies strategies and responsibilities to ensure safe and judicious use of medicines.
The Professional Services Review Scheme	The Australian Government facilitates compliance with the National Medicines Policy and the QUM. The PSR can involve scrutiny of a health care professional's practice and can implement restrictions if problems are identified.
The Pharmaceutical Benefits Scheme	The PBS is a central component of the Australian Government's management of prescribed medicines, governing access to and affordability of medicines. Specified medications are subsidised under the scheme.[281]

Translation of the relevant policies and procedures into practice is overseen and/or facilitated by professional bodies, such as the Pharmacy Board of Victoria, the Nurses Board of Victoria and the Medical Practitioners Board of Victoria. These Boards have developed standards of practice and procedures, which include recommendations on the parameters within which certain drugs should be prescribed and dispensed. These aim to complement, and ensure application of, national and state policies and statutory requirements. Other groups (for example, the Royal Australian College of General Practitioners (RACGP) and the Pharmaceutical Society of Australia (PSA)) have developed practice guidelines, learning objectives and training courses and resources that assist in the development of good prescribing and dispensing practices by the relevant professionals. A common theme communicated by these professional

281 See also the role of the Therapeutic Goods Administration (TGA) and its various committees, as discussed in Chapter 6.

bodies is that they are stewards or custodians of drugs and poisons. For example, the PSA (Victorian Branch) has summarised this as follows:

> In addition to contributing to the quality use of medicines, pharmacists have a major responsibility to be custodians of drugs, poisons and controlled substances for the community. They are expected to act honourably and carefully at all times to ensure that…(these substances)…are kept secure from unauthorised access and that they are supplied only to people who are lawfully entitled to receive them.
>
> A difficult practical problem that regularly confronts all pharmacists from time to time is their responsibility for being vigilant for the possibility of forgery, employed as a means of obtaining drugs for illicit purposes (Lloyd, Guibert & Bell 2000, p.v).

Similarly, in their submission to the Inquiry, the Australian Medical Association (AMA) noted that:

> In the most fundamental terms the most important principle underpinning medical practice is the ancient dictum, *primum non nocera*, first do no harm, whether this be by omission or commission…our primary concern is that we do not cause harm because of poor prescribing related to known patient allergies, predictable drug interactions, or likely side-effects given the expected disposition of the patient to such an outcome.
>
> Medical practitioners also have real concerns about prescribing to patients, where it subsequently transpires there is no valid clinical reason to do so and the related problem of diversion of the prescriptions to non-medical uses…[282]

The AMA also noted the challenge in this latter task:

> At a practical day-to-day level individual doctors face much more complex decisions about the treatment of some patients. A proportion of patients are deliberately, and often with considerable expertise, deceptively misrepresenting illnesses to doctors so as to access certain prescription pharmaceuticals such as opioid analgesics or benzodiazepines.[283]

The specific functions, duties and roles of these bodies with regard to the oversight of prescribing and dispensing practice will be discussed in greater detail later in this chapter. The next section, however, re-examines briefly the relevant state legislation and associated regulations specifically in the context of the prescription of Schedule 4 and Schedule 8 drugs and medicines.

282 Submission of the Australian Medical Association to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

283 Submission of the Australian Medical Association to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

Drugs, Poisons and Controlled Substances Act and regulations

Chapter 6 outlined the regulatory framework for drug control in Australia. This discussion also provided the legal context for prescribing and dispensing pharmaceutical medicines in Victoria. The following section examines the roles of medical practitioners and pharmacists in complying with these rules and regulations. In so doing, it is pertinent to revisit some of the key aspects of the *Drugs and Poisons and Controlled Substances Act 1981* and Regulations 2006 that have particular relevance to prescribing medicines, including those that are considered in this Inquiry.

Access to, and advice about, drugs and poisons is determined by their classification or Schedule (as indicated in Chapter 6, there are nine Schedules of drugs and poisons) and whether or not they are considered to be 'drugs of dependence' by the relevant state/territory authorities. A person may become dependent due to non-medical use of drugs, including legal drugs (for example, alcohol) and illegal drugs (for example, heroin). A patient may also become dependent on drugs that have been prescribed for legitimate purposes (for example, pain management). While there is some variance in the laws from jurisdiction to jurisdiction, it is not lawful to prescribe a drug simply to maintain a patient's dependence on a drug, except where special permission has been granted to an authorised medical officer (for example, those who prescribe methadone or buprenorphine for the purpose of pharmacological management of opioid dependence) for a specific patient.[284] This is to ensure coordinated treatment of the patient and to reduce the risk of 'doctor shopping' or over-prescription and diversion.

Prescribing Schedule 4 and Schedule 8 drugs

There are limitations on the duration that Schedule 8 drugs can be prescribed without an authorisation – usually for no more than two months.[285] There are also usually limitations on the geographical origin of prescriptions. For example, in Victoria a pharmacist cannot supply a Schedule 8 drug on a prescription written by a practitioner who is not registered in Victoria.[286] There are also guidelines on how prescriptions are written – to avoid intentional or unintentional errors. For example, prescriptions must state figures (that is, number of tablets or doses and dosage) in words and figures, to reduce the chances of fraud and the prescriber should not leave a space between the end of the prescription and the doctor's signature to avoid fraudulent additional entries (Bird 2006).[287] The practices that are expected of prescribers and pharmacists in relation to these drugs are clearly communicated. For example, the Guide to the Drugs Poisons and Controlled Substances Regulations 2006

284 See Section 35, *Drugs, Poisons and Controlled Substances Act 1981*.

285 See generally Division 10 of the *Drugs, Poisons and Controlled Substances Act 1981*.

286 See Regulations 15–17, Drugs, Poisons and Controlled Substances Regulations 2006.

287 See generally Drugs, Poisons and Controlled Substances Regulations 2006.

provided by DHS Victoria states that prescribers and pharmacists should ensure that:

- Reasonable steps are taken to ascertain the identity of a patient; and
- Appropriate authorisations have been attached (for example, imprint of pharmacy stamp, completed PBS Repeat Authorisation) (DHS Victoria 2006a, p.2).

In relation to broader uses of these drugs, DHS Victoria has produced the following guidance:

> Schedule 8 poisons (labelled Controlled Drug) are drugs with more strict legislative controls, eg. Morphine (Kapanol, MS-Contin), pethidine, oxycodone (Oxycontin, Endone), methadone (Physeptone), hydromorphone (Dilaudid), flunitrazepam (Hypnodorm), fentanyl (Durogesic). A permit might be required before prescribing Schedule 8 poisons…
>
> Schedule 4 poisons (labelled Prescription Only Medicine) include all other drugs for which prescriptions are required, eg. Diuretics, oral contraceptives, antibiotics, some compound analgesics (Panadeine Forte) & many others.
>
> The term "drugs of dependence" is used to describe all S8 poisons plus those S4 poisons that are subject to misuse and trafficking….Doctors should take additional precautions before prescribing Schedule 4 drugs of dependence (DHS Victoria 2006b, p.1).

and

> Before prescribing a drug of dependence, a prescriber must take all reasonable steps to ensure a therapeutic need exists and to ascertain the identity of a patient (DHS Victoria 2006b, p.2). (Emphasis in the original)

Statutory bodies in the various jurisdictions have requirements regarding notification of dependent patients. For example, in Victoria:

> Where there is reason to believe a person is a drug-dependent person, a medical practitioner must notify the Department of Human Service (DHS) Drugs and Poisons Regulation Group (DPRG) in the prescribed form (DHS Victoria 2006c, p.1).

State and territory governments therefore set policies and procedures for prescribing S8 drugs to include a clear focus on the need to adopt strategies to avoid/reduce misuse and diversion. One particular example of such a policy is the Victorian 'Policy for Maintenance Pharmacotherapy for Opioid Dependence' (DHS Victoria 2006d). This document states that various factors related to illegal drug use

> …can create a risk of diversion of prescribed doses for illicit or unsanctioned use (DHS Victoria 2006d, p.6).

Only authorised practitioners can prescribe for these purposes to specifically identified patients. The policy describes the necessary expertise and assessment processes for a medical practitioner to be authorised to prescribe methadone

and buprenorphine and identifies the treatment procedures and context for safe practice (for example, maximum number of patients). The policy alerts practitioners to the risks of these drugs if not used in a manner consistent with the policy and other guidelines.

The policy also suggests preventive countermeasures such as:

- advise the patient of the considerable risks of misuse of psychoactive drugs (such as the benzodiazepines) and alcohol while on pharmacotherapy
- ask the patient to sign a Medicare Australia privacy release form to enable access to information about the provision of Pharmaceutical Benefits Scheme drugs from other doctors and pharmacists
- conduct a drug screen of supervised urine collections (DHS Victoria 2006d, p.12).

Specifically in relation to diversion and misuse, the policy emphasises a range of required and advised strategies, including dose dilution for methadone, supervised dosing for methadone and buprenorphine and the potential benefits of prescribing the recently available combination product of buprenorphine/naloxone.[288]

As discussed below, other national and state statutory bodies and professional organisations communicate similar unambiguous advice. However, as indicated earlier in this chapter, implementation of such advice may be more challenging.

Medicare Australia and the Pharmaceutical Benefits Scheme

Medicare Australia (until recently called the Health Insurance Commission) has a central role regarding access to drugs considered in this Inquiry. Located within the Australian Government Department of Health and Ageing (DoHA), Medicare Australia is responsible for, among other things, Quality Use of Medicines, the Professional Services Review Scheme and the Pharmaceutical Benefits Scheme (PBS). The Department of Veterans Affairs (DVA) has similar responsibilities related to the services provided to veterans.

Medicare Australia relies on advice and input from a variety of stakeholders such as state and territory governments, health professionals and consumers. For example, the Australian Pharmaceutical Advisory Council (APAC) is a consultative group of key stakeholders that includes nurses, pharmacists, medical staff, government personnel and representatives of the pharmaceutical industry.

> The Council identifies and considers issues and needs in health care with particular reference to pharmaceuticals. In this role, the Council can comment on, review or endorse guidelines (DoHA 2006a, p.1).

288 If taken by a dependent opioid user, this latter product will result in withdrawal symptoms if diverted and injected, but not if taken orally as indicated. See Chapters 2 and 9.

Medicare Australia functions in the context of the National Medicines Policy (DoHA 2000), which directly influences a number of procedures including the Quality Use of Medicines and the PBS.

Quality Use of Medicines

In Australia, Quality Use of Medicines is a cornerstone of safe and effective prescribing and is a critical component of the Australian National Medicines Policy. This includes core statements that medicines should be used:

- Judiciously – medicines, whether prescribed, recommended, and/or self-selected should be used only when appropriate, with non-medicinal alternatives considered as needed;
- Appropriately – choosing the most appropriate medicine, taking into account factors such as the clinical condition being treated, the potential risks and benefits of treatment, dosage, length of treatment, and cost;
- Safely – misuse, including overuse and underuse, should be minimised; and
- Efficaciously – the medicines must achieve the goals of therapy by delivering beneficial changes in actual health outcomes (DoHA 2000, p.3).

Quality Use of Medicines involves a range of strategies related to policy development, education and training and strategic research, and emphasises the importance of routine data collection. The Australian Quality Use of Medicines identifies the role of a number of stakeholders, including medical staff, pharmacists, other health staff, consumers, the media and the broad community. The National Strategy for Quality Use of Medicines describes specific responsibilities and roles for each group, and overall responsibilities have been described in the following way:

> All partners are responsible for:
>
> - Improving medication use by recognising when and where problems exist, identifying factors that contribute to those problems, initiating interventions to improve medication use, and evaluating outcomes;
> - Enhancing understanding of the risk and benefits associated with the use of all medicines (DoHA 2004, p.10).

While the Quality Use of Medicines is aimed at safe and effective use of all medicines, the aims have particular resonance for drugs being considered as part of this Inquiry. As succinctly noted by Carr, this presents a practical clinical challenge, a theme that consistently emerges in international and national literature on this issue:

> The aim is to try and prevent the prescription of drugs that are going to be abused rather than used in a controlled and reasonable way. Thus the aim is not to deny nitrazepam or temazepam to the regular patient who is known to be using one or two tablets a day (though there may be other appropriate

> management strategies here). The aim is the prevention of 'doctor shopping', the acquisition of multiple prescriptions and abuse of 20, 30 or more tablets a day (Carr 2000, p.2).

Adherence to the Quality Use of Medicines is likely to reduce the risk of pharmaceutical misuse and reduce unintentional impact on patients who may benefit from these medicines.

Professional Services Review Scheme

The Quality Use of Medicines also needs to be considered in relation to the Australian Government's Professional Services Review Scheme. This project aims to:

> protect the integrity of the Commonwealth Medicare Benefits and Pharmaceutical Benefits programs and in doing so:
>
> - protects patients and the community from the risks associated with inappropriate practice; and
> - protects the Commonwealth from having to meet the cost of services provided as a result of inappropriate practice (Medicare Australia 2005, p.1).

The Professional Services Review Scheme can examine the behaviour and procedures of individual practitioners who have been identified as potentially engaging in procedures that are not consistent with Quality Use of Medicines. The Professional Services Review Scheme involves a process of peer review of practitioners as described in the following:

> Medicare Australia, whose role and function is to administer the MBS (Medicare Benefits Scheme) and PBS, may request the Director of PSR to review the provision of services by practitioners who are suspected of engaging in inappropriate practice.
>
> Medicare Australia identifies practitioners whose MBS or PBS data indicates that their rendering, initiating or prescribing practice profiles appear different when compared with their peers. A Medicare Australia Case Management Committee (CMC) in each state regularly reviews these profiles and will decide if there is sufficient concern to commence Medicare Australia's practice profile review process (Medicare Australia 2005, p.1).

The review process consists of two stages. The first stage involves information gathering to ascertain how a medical practice operates. This stage also provides a practitioner who is under review an opportunity to respond to any concerns. If the response to these is adequate, the process can end at this point. The second stage involves an interview with the practitioner, resulting in a written report. Again the practitioner has the opportunity to respond in writing and if the concerns are dealt with, the process ends. However, the process may also result in a review of the practitioner's right to engage in certain practices or services, such as changing his or her prescribing authorities.

The above process relates to quality clinical practice. Of course occasionally clinicians may deliberately engage in fraud and under the *Medicare Australia Act 1973*, Medicare Australia can, alone and in conjunction with other stakeholders (for example, the police), investigate fraud by professionals and by members of the public.

In concert with other procedures to ensure adherence to the Quality Use of Medicines, it is evident that these processes rely on quality information systems, both to alert the Professional Services Review Scheme to potentially risky practices and to inform judgements about the nature of individual practices and procedures.

The Pharmaceutical Benefits Scheme (PBS)

The Pharmaceutical Benefits Branch and the Pharmaceutical Access and Quality Branch of the Australian Government DoHA jointly manage policy relating to the PBS. For approximately six decades the PBS has been a central component of the Australian Government's management of prescribed medicines, governing access to and affordability of medicines. At a cost of $6 billion per year, the PBS is applied to approximately 80 per cent of all medicines prescribed in Australia, covering some 170 million prescriptions in the financial year 2004–2005 (DoHA 2006a).

The PBS is used to facilitate access to identified medication by removing potential cost barriers – that is, by subsidising costs to patients according to set schedules for specific drugs. Thus, consistent with the National Medicines Policy, the PBS aims to ensure improved health outcomes in relation to access to medicines, in the context of economic/efficiency concerns such as avoiding cost shifting, ensuring value for money effectiveness and affordability in selected medicines. The policy also focuses on judicious use of medicines.[289]

The Schedule of pharmaceutical benefits for approved pharmacists and medical practitioners

This Schedule, which is regularly updated, identifies the relevant drugs, controls, processes, and requirements for medical staff and pharmacists who prescribe and provide controlled drugs. That is, the Schedule lists the medicines available under the PBS and specifies how they can be used. Medicines may still be available outside this Schedule, but they will not be subsidised under the PBS.

As discussed in Chapter 6, only products registered on the Australian Register of Therapeutic Goods (ARTG) are considered for listing on the PBS. The ARTG is a database of medicines/therapeutic drugs (and devices) that have been approved for use in Australia through the Therapeutic Goods Administration (TGA). The TGA:

289 For a comprehensive account of the PBS, see Duckett 2004.

> Carries out a range of assessment and monitoring activities to ensure that all therapeutic goods available in Australia are of an acceptable standard. At the same time, the TGA aims to ensure that the Australian community has access, within a reasonable time, to therapeutic advances (DoHA 2006b, p.1).

After review by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body with a membership that includes medical practitioners, other health staff and a consumer representative, a medicine may be placed on the PBS list. The PBAC will recommend the maximum quantity and number of repeat prescriptions. There are three broad categories of PBS drugs, each category related to the degree of restriction or required authority that may relate to any prescription, dosage, quantity, duration of treatment and/or repeat prescriptions. The practitioner (for example, a GP) has to apply for the authority to prescribe outside these guidelines. The categories are:

- Unrestricted benefits – there are no restrictions on therapeutic use through the PBS;
- Restricted benefits – a drug can be prescribed through the PBS when the practitioner is satisfied that the clinical condition matches the approved therapeutic uses of the medicine; and
- Authority-required benefits – a drug can be prescribed through the PBS when the practitioner is satisfied that the clinical condition matches the approved therapeutic restrictions and prior approval is provided by Medicare Australia (or DVA for the treatment of veterans). For some drugs there are 'continuation criteria' for continued treatment. Concerns about abuse potential (as well as other factors such as cost) have informed decisions to designate a medicine as 'Authority required'. Only medical practitioners (not dentists) can write 'authority-required prescriptions'[290] (DoHA 2006c).

With regard to 'drugs of dependence and addiction' the Schedule states that**:**

> Prescribers must heed State/Territory laws when prescribing drugs listed as narcotic, specified or restricted and must notify, or receive approval from the appropriate health authority (DoHA 2006c, p.35).

The Schedule also describes the application of the following guidelines:

- the maximum quantity authorised is generally for one month's therapy (e.g. one week's therapy with three repeats);
- where supply for a longer period is warranted, quantities are usually for up to three months' therapy;
- telephone approvals are limited to one month's therapy (DoHA 2006c, p.37).

290 Authorities-to-prescribe under the Commonwealth PBS are not to be confused with the permits that must be obtained to prescribe or dispense drugs of dependence under the state *Drugs, Poisons and Controlled Substances Act 1981*. See Chapter 6 for further discussion.

The following list, using specific medicines as examples, illustrates conditions and requirements that must be complied with before authorities-to-prescribe are granted. It is important to note that these are attenuated summaries and do not include the full information provided in the Schedule:

Temazepam:	The maximum quantities and/or repeat prescriptions for temazepam are not granted except as detailed. For example, an Authority may be given when temazepam is to be used for malignant neoplasia (late stage) where patients are receiving long-term nursing care on account of age, infirmity or other condition in a residential facility (for example, hospital; nursing home) and are demonstrated to have recent (last 6 months) dependence on benzodiazepines and have not responded to gradual withdrawal. The Authority specifies the maximum dose and quantity (for example, 25 x 10mg tablets). Authority may also be granted for the treatment of insomnia in palliative care. Authority may be for the initial supply (up to 4 months) for patients where insomnia is a problem and continued supply may be authorised where consultation with a palliative care specialist or service has occurred.
Alprazolam:	May be authorised when panic disorder has been diagnosed and where other treatments have failed or are inappropriate.
Bromazepam:	May be authorised for patients with terminal disease or patients with refractory or anxiety states. However, the drug is for short-term use and palliative care, and should not be used as a 'first line of treatment' – other benzodiazepines should have been tried and found to be ineffective or otherwise inappropriate. Increased quantities and/or repeats may be granted to patients with terminal disease and other patients who are dependent and for whom gradual withdrawal has not been effective.
Oxycodone:	There is a high risk of dependence. Authority for increased maximum quantities only granted for severe disabling pain associated with malignant neoplasia or chronic disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is for less than 12 months.
Morphine sulphate:	There is a high risk of dependence. Authority for increased maximum quantities only granted for severe disabling pain associated with malignant neoplasia or chronic disabling pain not responding to non-narcotic

> analgesics where the total duration of narcotic analgesic treatment is for less than 12 months. Authority required for use in chronic and severe disabling pain due to cancer (200mg controlled release tablet or sachet of controlled release granules) (DoHA 2006c).

These examples give an indication of the way in which the PBS Schedule and processes can be used to control access to particular medicines, given doses, quantities and duration of treatment. This obviously has relevance for reducing the risks from medicines that may be misused, including those under consideration by this Inquiry.

Medicare Australia and the 'doctor shopping' or 'prescription shopping' service

A key element of pharmaceutical diversion has been described as 'doctor shopping' or 'prescription/pharmaceutical shopping'.[291] Such behaviours may occur to support an individual's own misuse. 'Doctor shopping' may also be used to accumulate drugs that are then sold onto the black market. The Pharmacy Board of Victoria provided an illustration of how one individual can access an enormous number of controlled drugs, reporting on the success of a patient, in his mid-40s, who managed to obtain over 18,000 capsules (temazepam), over a 12-month period, from over 130 doctors and 95 pharmacies (Pharmacy Board of Victoria 2003).

Various 'prescription shopping' programmes have been implemented to respond to this problem, and the latest iteration has been referred to as the 'Prescription Shopping Program', initiated by Medicare Australia.

> The Prescription Shopping Program is one of a number of initiatives administered by Medicare Australia to facilitate the proper and sustainable use of the Pharmaceutical Benefits Scheme (PBS). …
>
> The authority to administer the Prescription Shopping Program has been conferred upon Medicare Australia by Section 30 of the Medicare Australia (Functions of the Chief Executive Officer) Direction 2005.[292]

The programme aims to identify patients who, within a three-month period, have:

(a) PBS items prescribed to them by 6 or more different prescribers (excluding specialists and consulting physicians); or

(b) Obtained a total of 25 or more target PBS items; or

(c) Obtained a total of 50 or more PBS items.

291 See Chapter 5 for further discussion of the practice of 'doctor shopping'.

292 Submission of Mr Colin Bridge, A/g General Manager, Program Review Division, Medicare Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

> The target PBS medicines include analgesics, antiepileptics, anti-Parkinson medicine, psycholeptics, psychoanaleptics (including antidepressants), and all other nervous system medicine.[293]

Any such programme can raise concerns about privacy and confidentiality. This programme, however, addresses these issues, for example by ensuring that information is only provided by email if appropriate encryption software is installed. Further:

> Information will only be disclosed about patients identified under the Program's criteria. Strict privacy guidelines are in place and patient details are limited to PBS items supplied to a patient in the 3 month period for which they were identified.[294]

The programme was established at the beginning of 2005, and by June 2006 there were 11,705 medical practitioners registered with the service. Registration with the service results in access to information. That is, these doctors can seek patient information via telephone if:

> they suspect (them) to be obtaining PBS Medicine in excess of medical need,

in relation to:

> (a) whether or not a patient has been identified under the Program's criteria, and
>
> (b) the details of PBS items supplied to a patient in the 3 month period for which they were identified.[295]

Complementing inquiries by medical practitioners, Medicare Australia may contact a practitioner through a Medicare Australia Compliance Pharmacist to alert them that a patient may be obtaining PBS medicines 'in excess of medical need'.

> Once a patient is identified for intervention under the Program, a Patient Summary Report including information on the number of PBS items prescribed to that patient over a 3 month period is made available to prescribers of the identified patient. This information is made available to assist when prescribing to these patients.

293 Submission of Mr Colin Bridge, A/g General Manager, Program Review Division, Medicare Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

294 Submission of Mr Colin Bridge, A/g General Manager, Program Review Division, Medicare Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

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> Under the Prescription Shopping program an average of 23,000 patients are identified each quarter and 4% are intervened with by a Medicare Australia Compliance Pharmacist.[296]

By June 2006, on average the service was responding to over 250 inquiries per week.

New formulations and products

With the expressed intention of improving therapeutic outcomes and reducing side effects, pharmaceutical companies are constantly developing new products and revised formulations for existing products. New products may have medical benefits, but they should also be examined to assess the risk for deleterious and unforseen consequences. This issue is now being recognised overseas. For example, in the United States:

> Now nearly every product of abuse is required to have at least an evaluation of risk at the time of application…Risk management programs may address elements such as the package insert, proper patient selection, education of patients and healthcare providers, assessment for diversion along the distribution chain to the patient, post-marketing surveillance, and definition of and specific restrictions on marketing practices. The intensity of the program is generally tailored to the degree of perceived risk (McCormick 2006, p.S66).

It may be worthwhile to consider the merit of such strategies in Australia.

Another deliberate strategy to reduce the abuse potential is the reformulation of drugs by pharmaceutical companies. Reformulation can include:

> ...combination products with an oral formulation of opioid with antagonist, formulations with other aversive characteristics…physically impenetrable formulations, and drug device combinations with patient recognition capability (McCormick 2006, p.S66).

Common examples of such strategies include:

- formulations that affect the solubility of a drug (thereby reducing the potential for injection);
- adding a drug such as naloxone to buprenorphine. This means that if such a drug is injected an opioid dependent person will experience withdrawal symptoms, but will not experience such an outcome if the drug is taken as intended; or
- adding a dye, to prevent surreptitious administration of a drug by a sexual predator.

Each approach presents some challenges and indeed historically drug misusers have ignored some of these strategies (resulting in injection of insoluble matter –

296 Submission of Mr Colin Bridge, A/g General Manager, Program Review Division, Medicare Australia, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

see Chapter 4) or otherwise found ways around such preventive measures (see for example Schuster 2006).

It is beyond the scope of this Interim Report to examine these various methods in detail, but certainly this is an issue that merits further review in the future.[297]

Professional practice, standards and accountability

In addition to the various processes available to the Australian and state/territory governments, national and state professional bodies have a significant role in ensuring safe and effective use of all medicines in general and specifically those that are the concern of this Inquiry. Three Victorian Boards are used to illustrate these roles:

The Pharmacy Board of Victoria;

The Medical Practitioners Board of Victoria; and

The Nurses Board of Victoria.

The Pharmacy Board of Victoria

The Pharmacy Board of Victoria is established and appointed under the *Pharmacy Practice Act 2004*. It consults with and responds to the advice of the Minister for Health. The Board aims to promote safe dispensing and use of medicines, and minimise the community's exposure to health risks associated with the provision of pharmacy services. The Board has determined minimum standards of good practice, and monitors and administers duties and responsibilities under the relevant Acts and regulations. Recently it has developed the *Guidelines for Good Pharmaceutical Practice* (Pharmacy Board of Victoria 2004). These guidelines cover registration, training, responsibilities and management of drugs that are subject to misuse. For example, there are requirements to report prescribing of excessive quantities of S4 and S8 drugs to the DHS.

The Board has procedures and resources that are directed to ensure safe and effective dispensing. For example, the Board will conduct a thorough review of pharmacists who are identified as behaving outside of legislative and professional guidelines – in short, engaging in risky practices (Pharmacy Board of Victoria 2004). The Board also liaises with the Medical Practitioners Board of Victoria to ensure that pharmacists are informed about medical practitioners who have had prescribing limitations imposed. Other relevant activities include developing standardised procedures for reporting suspicious purchases of medicine (for example, pseudoephedrine which may be diverted for use in the manufacture of illegal amphetamines) and producing newsletters that advise on quality practices, including those that aim to reduce forgery and misuse of medicines.

297 A recent meeting convened by the College on Problems of Drug Dependence (CPDD) will provide some guidance on this issue (see Grudzinskas et al. 2006).

Medical Practitioners Board of Victoria

The Australian Medical Council and state Medical Boards have oversight of medical standards and registration of practitioners. The Council is an independent national standards body that accredits education and training programmes. Each jurisdiction has a Medical Board, which is responsible for medical registration. The Boards aim to ensure that only properly trained and skilled doctors are registered and that registered doctors perform within expected standards of conduct and competence. The Boards respond to complaints about individual practitioners, and under the relevant legislation they can investigate and, where indicated, discipline medical practitioners, including limiting their rights to practise (Medical Practitioners Board of Victoria website).

In this context, the Medical Practitioners Board of Victoria is an independent statutory authority that has responsibility for professional standards, using non-disciplinary and disciplinary methods to work with medical practitioners who are not performing to established standards and expectations. One issue that may be a concern is that medical practitioners may be at an increased risk of prescribing for their own use.[298] The guidance on this is unambiguous:

> Doctors are not permitted to prescribe Schedule 8 or Schedule 4 poisons for the purpose of self-administration (regardless of whether the treatment was initiated by another medical practitioner) (DoHA 2006b).

Doctors who do experience problems in relation to their personal use of these drugs may be investigated by the Board and may also be referred to services established to help them. One such example is the Victorian Doctors Health Program. This is:

> an independent legal entity that has been established to provide a full time professional service to meet the needs of sick and impaired doctors and medical students (Doctors Health Database (Victoria) website).

The Nurses Board of Victoria

The Nurses Board of Victoria is a self-funded statutory authority, incorporated under the *Nurses Act 1993*. It consists of 12 members, appointed by the Minister for Health.[299] The Board regulates the nursing profession, but also addresses the wellbeing of nurses. This latter point is relevant because, like medical practitioners, the nursing profession has been identified as potentially high-risk for pharmaceutical misuse due to a number of factors, including access.

The Nurses Board noted, in its submission to the Inquiry, that in Victoria there are 78,000 nurses registered with the Board. In this context they observed that

298 See Chapter 4 for a discussion of the adverse consequences of pharmaceutical use and Chapter 5 for a brief discussion of misuse by health professionals.

299 Submission of the Nurses Board Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

in 2004–2005 there were a total of 23 complaints heard by the Board that involved the misuse/abuse of medications, including the misappropriation of medications from the workplace. Most commonly these cases involved 'benzodiazepines and narcotics'. While only a small proportion of the total number of nurses have been identified in such cases, it is a concern on two counts. First, the risk to the individual nurse and second, because nurses may be a potential source of diverted pharmaceuticals to other people. However, there is little information that can help identify if this potential risk is realised.

The Board also commented that the number of cases they have identified could be an underestimation:

> The Board is aware that not all incidents are reported to the Board, including some situations where the employer chooses to manage the incident within the employment relationship.[300]

And they also expressed the view that:

> Any matter involving the misappropriation and taking of drugs by a registered nurse should be reported to the Nurses Board of Victoria.[301]

Exposure to workplace factors that increase the risk of pharmaceutical misuse require a range of responses, including strategies to reduce risk, respond to breaches of legal and employment responsibilities and address the personal needs of the affected professional. In relation to the latter, in their submission the Board also noted the imminent commencement of the 'Victorian Nurses Health Program', where nurses will be encouraged to self-report for assistance if they have a drug or other health problem.

These examples indicate that various professional boards can have an important role in ensuring safe and effective use of pharmaceuticals and in preventing their misuse. Clearly the Boards discussed above have identified this as an important role, both in relation to their community responsibilities and to ensure the wellbeing of their members.

Professional practice guidelines and policies

In addition to legislative approaches and policies that determine standards of practice, various expert groups and professional bodies have developed guidelines, learning objectives, courses and other materials that aim to ensure safe and effective prescription of medicines. These may be important adjuncts to legislation and regulations.

International bodies such as the World Health Organization (WHO) have developed a Guide to Good Prescribing Steps. Although not specific to drugs

300 Submission of the Nurses Board Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

301 Submission of the Nurses Board Victoria to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

that are the focus of this Inquiry, they clearly have relevance to them. These guidelines describe the following steps (adapted from Shakib & George 2003):

1. Make a diagnosis;
2. Set the therapeutic goal for the individual patient;
3. Decide on the therapeutic approach;
4. Choose a drug class (clearly where medication use is indicated);
5. Choose a generic drug within that class;
6. Individualise dose, formulation, frequency and duration (that is, for the individual patient);
7. Verify the suitability of the chosen drug;
8. Write the prescription;
9. Inform the patient;
10. Monitor for effects and adverse effects; and
11. If necessary alter the prescription.

The Australian Government DoHA has also fostered the development of clinical guidelines, learning objectives and assessment procedures to ensure safe and effective treatment for opioid dependence (Allsop et al. 1997; Allsop et al. 2004; Henry-Edwards et al. 2003). As well as addressing issues such as assessment, induction and maintenance strategies for safe and effective pharmacological management of opioid dependence, these resources also identify the importance of responding to drug-seeking behaviour and diversion. For example, while acknowledging the potential benefits of 'takeaway' doses of methadone, the guidelines note that:

> Uncontrolled access to takeaway doses is associated with greater diversion and adverse consequences including bringing the program into disrepute. The safety of takeaway doses of methadone is increased by:
>
> - Careful selection of patients suitable for takeaway methadone (requiring close monitoring by the prescriber and dispenser).
> - Education of the patient (Henry-Edwards et al. 2003, p.20).[302]

Thus, the guidelines recommend that, generally, methadone should be consumed under supervision, and where takeaway doses are provided this should only occur with patients who are carefully selected and monitored. The number of consecutive takeaway doses should be limited. They note that the rationale for this caution is that:

> - Research into methadone related deaths has consistently shown that between one third and two thirds of all methadone related deaths occurred in persons not prescribed methadone treatment.

302 There are sometimes grounds to prescribe doses that are taken outside normal supervisory procedures – for example, for stable patients who are employed and who have difficulty attending every day for their pharmacotherapy (Henry-Edwards et al. 2003).

- The major source of diverted methadone is take away doses prescribed for patients in MMT (methadone maintenance treatment) (Henry-Edwards et al. 2003, p.30).

Similarly, the RACGP has developed Guidelines on the prescription and use of benzodiazepines. The stated rationale for these Guidelines was as follows:

> These Guidelines were formulated to provide assistance to general practitioners in relation to appropriate prescribing of benzodiazepines in the context of general practice. The Guidelines are based on the evidence regarding the advantages and disadvantages, particularly the danger of dependence, associated with the use of benzodiazepines (Royal Australian College of General Practitioners (RACGP) website, p.1).

Key aims of the Guidelines included:

- Reducing deaths from drug overdose; and
- Reducing indiscriminate prescribing of benzodiazepines to polydrug users.

In addition to being consistent with the National Medicines Policy, the Guidelines 'state general principles based on the best available evidence' (RACGP website, p.1). The Guidelines are outlined below in Figure 7.1

Table 7.2: RACGP guidelines on the prescription and use of benzodiazepines

1. Wherever possible avoid prescribing benzodiazepines especially to known polydrug users, including those with dependence.
2. When a programme of benzodiazepine reduction is undertaken it should be with the patient's consent and co-operation.
3. All patients prescribed benzodiazepines should be advised of the risk of dependence associated with long-term use.
4. Patients receiving prescriptions for benzodiazepines should be advised to obtain all such prescriptions from the same doctor, wherever possible, so that risk of dependence may be monitored.
5. Treatment review should include a review of the indication(s) for continued use of the benzodiazepine, medication dose and possible adverse effects. For all patients receiving long-term benzodiazepines review is particularly relevant.
6. Non-medication management for conditions such as anxiety and insomnia includes clarification of the problem, counselling and specific advice, with referral where the diagnosis is uncertain, or where assistance in management is required.
7. Detoxification from benzodiazepines may be facilitated by changing patients to long half-life medications eg diazepam, and then slowly reducing the dose. One-to-one counselling may be supplemented by self-help support programmes during withdrawal.
8. The management of anxiety and insomnia should rely largely on non-pharmacological interventions.
9. When benzodiazepines are prescribed, the lowest dose to achieve the desired outcome for the shortest duration necessary should be provided.
10. For residents of aged care facilities, discontinuation of benzodiazepines can often be achieved gradually, provided patient, family and nursing staff are cooperative. Medication may occasionally be required to control anxiety, agitation or other disturbed behaviours. Staff should be knowledgeable in appropriate management of challenging behaviours.

Source: Royal Australian College of General Practitioners (RACGP) website, p.1.

To ensure compliance with the Guidelines, doctors are advised to undertake and keep a record of the following steps:

- Undertake a full patient history, including focus on other drug use and co-existing mental health problems;
- Conduct an adequate physical examination;
- Identify/diagnose problems; and
- Develop a management plan.[303]

Similarly, the Pharmacy Board of Victoria provides guidelines for pharmacists on methadone, buprenorphine and other opioid treatment. These guidelines identify the importance of close liaison with prescribing doctors, describe where dosing should take place and enunciate key procedural issues such as ensuring adequate security for medicines, providing an accessible written manual on procedures, establishing complaint resolution procedures and maintenance of proper record systems. The guidelines state that:

> Pharmacies providing an Opioid Substitution or Antagonist Treatment Service shall maintain:
>
> (a) a recording system which enables pharmacists to access client information including the dose from their current prescription and a photograph for identification;
>
> (b) day or incident reporting books or similar;
>
> (c) client treatment notes. It is recommended that pharmacists maintain written notes detailing dose alterations, missed doses, consultations with prescribers etc.;
>
> (d) drugs, harm minimisation and other appropriate literature for distribution by the pharmacists to the client; and
>
> (e) required references including the National Clinical Guidelines and Procedures for the use of buprenorphine in the treatment of heroin dependence, the National Policy on Methadone Treatment, Methadone

303 The importance of developing a management plan was testified to by Dr Mike McDonough of Melbourne's Western Hospital when he gave evidence to the Committee in July 2006. He stated: 'I think a treatment plan is absolutely essential. Unfortunately, seeing some of the cases where things did go wrong, I cannot remember ever seeing a case where the doctors involved kept notes that indicated there was a treatment plan, and it is probably the most important and most commonly overlooked aspect of the care of these patients. These are, again, benzodiazepine-dependent patients who sometimes use multiple doctors or doctor shop and get into problems with the way they take these medications.

The treatment plan should always involve one doctor and one pharmacist – that is, one dispensing point – and ideally one or other pharmacies working around the clock or working different days, getting to know the patient and picking up on some days where the patient does not look well. [In such cases] they may choose not to dispense until the patient has been sent down to the GP. Something like that is a regularly used technique in the management of patients on a methadone program, but it is probably not that familiar to many GPs. So it is just an additional form of monitoring – checks and balances' (Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 13 July 2006).

> Treatment in Victoria Pharmacy Board of Victoria – Guidelines 2004 (amended) (Pharmacy Board of Victoria 2004, p.32).

The guidelines also contain general comments about the role of the pharmacist in relation to medicines subject to abuse:

> **a**. Pharmacists must keep themselves aware of any drugs or medicines which are being abused or misused in the general community and in the area in which they usually practise and ensure that any requests received at their practices for such drugs or medicines are referred to a pharmacist who must be assured that the drug or medicine is to be used for a bona fide therapeutic purpose before supplying the drug or medicine.
>
> **b**. For the purpose of this guideline, pharmacists are expected to observe warnings or notices about drug or medicine misuse or abuse distributed to the pharmacy profession and to ascertain conditions in their local area by regular consultation with other pharmacists and other health professionals in the area (Pharmacy Board of Victoria 2004, p.62).[304]

304 Prescription guidelines are also advisable in particular locations and for particular circumstances. For example, in its submission to the Inquiry, the Victorian Institute of Forensic Mental Health suggested consideration of the following potential guidelines for benzodiazepine use in prisons:

'Guidelines on the clinical use of benzodiazepines in prisons would seem to need to fall somewhere between a zero tolerance stance and what currently occurs in the community. With this in mind, the following guidelines are suggested for benzodiazepine prescribing within prisons:

1. Assessment of the clinical indications for benzodiazepines should take account of the possibility of a history of benzodiazepine abuse, including where possible information from previous prescribers.
2. Prisoners requesting benzodiazepines should be educated on the indications, risks and benefits of these drugs, including the risk of dependency. This has been shown to be effective in reducing use amongst patients in the community.
3. Prisoners should be provided with alternative ways of treating their presenting complaint such as sleep hygiene education for insomnia or talking therapies for episodes of distress and anxiety.
4. Benzodiazepines should only be prescribed for the conditions for which they are known to be effective, at the minimum effective dose, avoiding benzodiazepines with a relatively short half life, and rarely prescribed for a period of more than three to four weeks, preferably on an intermittent, rather than regular basis.
5. Prisoners who are long term users should be withdrawn from benzodiazepines in a humane way. This would involve them collaborating with prescribers to work out a reduction regime which they can reasonably adhere to and which gives them a more realistic chance of staying abstinent from use in the future. A typical withdrawal regime can be found in the document Typical Withdrawal Plan in 'Guidelines for the Prescription of Psychotropic Drugs in Victorian Prisons'…
6. Long term maintenance use of benzodiazepines is not possible given the problems of trafficking and diversion of psychotropic medication. It is also difficult to accurately identify those who are truly long term maintenance patients from those who are not.
7. Prescribers should be aware of trends in benzodiazepine abuse within the local prison system and avoid the use of agents that are known to be highly valued for the purposes of diversion and trafficking. For example, in Victorian prisons – alprazolam and clonazepam.
8. Current evidence suggests that the combination of buprenorphine and alprazolam is associated with an increased risk of mortality' (Submission of Mr Michael Burt, Chief Executive Officer, Victorian Institute of Forensic Mental Health, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006).

It is important to note that guidelines are important, but limited, facilitators of evidence-based medicine (for example, see Allsop & Helfgott 2002; National Health Service Centre for Reviews and Dissemination 1999). They are not always embraced and do not always result in quality clinical practice. For example, one study (Mazza & Russell 2001) found that GPs generally do not access or follow guidelines. Even when they are adhered to, they might not on their own result in quality practice. Allsop and Helfgott (2002) cited one commentator who eloquently described the limitations:

> There is a fear that in the absence of evidence clearly applicable to the case in hand a clinician might be forced by guidelines to make use of evidence which is only doubtfully relevant, generated perhaps in a different grouping of patients in another country at some other time and using a similar but not identical treatment. This is evidence-biased medicine; it is to use evidence in the manner of the fabled drunkard who searched under the lamp for his door key because that is where the light was, even though he had dropped the key somewhere else (Grimley Evans 1995, p.461).

This limitation is acknowledged in the Victorian Policy for Maintenance Pharmacotherapy for Opioid Dependence:

> The policy is not intended to replace professional judgment in individual cases (DHS Victoria 2006d, p.2).

The other problem is that while some policies and guidelines are specific and detailed, others are not so clearly enunciated. For example, at the public hearings for this Inquiry Dr Harcourt, the Chief Health Officer of the Health and Disability Strategy Programs, Transport Accident Commission (TAC), noted that in relation to pain management:

> …there needs to be some benchmarking on the management of non-malignant chronic pain…there is no broad consistent clinical policy framework which pulls all that together in the management of chronic pain.[305]

These are not arguments to discount guidelines. They simply identify that there is a need to develop strategies to improve their effectiveness, to increase the likelihood of them being used by the target audience, and to combine their development and dissemination with other strategies that ensure judicious application of pharmacotherapies. This means providing treatment in the context of the individual patient's unique circumstances; for example, by simultaneously increasing practitioner understanding and acceptance of the rationale for the guidelines and supporting the development of quality clinical skills and supervision/support in their application.

305 Dr Peter Harcourt, Chief Health Officer, Health and Disability Strategy Programmes, Transport Accident Commission, Evidence to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 19 June 2006.

Other contributions from professional organisations

Professional bodies often contribute in other ways to reduce the risk of pharmaceutical misuse, such as by conducting research and surveys to inform the development and implementation of quality practice. As an illustration, the Australian PSA conducted research into prescription forgery (Lloyd, Guibert & Bell 2000). In a review of the data (from 1997–1999) they found that the majority of forgeries were for drugs considered by this Inquiry (eg. pethidine, temazepan, flunitrazepam, oxycodone, morphine tablets). They noted that while the majority of forgeries were for benzodiazepines, this could in part have been because the regulations governing access to most of these drugs may be lower than for S8 drugs (eg. morphine), as discussed earlier in this chapter and in Chapter 6.

The PSA also noted that there was a lack of coordinated data gathering (for example, they observed that police do not always record correct names of forged drugs in line with pharmacy reporting, creating difficulty for intelligence coordination). One of their conclusions was that there was a need to enhance the coordination of effort across the relevant statutory bodies and professional groups.

Contributions from pharmaceutical companies

Finally, it is relevant to note that many pharmaceutical companies provide guidelines and training related to quality use of medicines for medical practitioners and pharmacists. They may also provide financial or resource supports to facilitate training and quality practice initiatives by other groups. For example, in their submission to the Inquiry, Mundipharma made the following statement:

> Mundipharma, for its part, takes its responsibility to educate all participants in the distribution chain for opioid analgesic medication very seriously. We believe strongly that the effectiveness of laws governing the prescription and supply of controlled prescription products is only as good as the ability of individuals to comprehend the requirements and comply. Education around the rationale and need for various regulatory controls provides the basis for positive moral and ethical decision making by all stakeholders to understand and comply with the requirements. It is important for all stakeholders to understand that regulatory requirements imposed are not a bureaucratic exercise but, rather, are there to encourage modified behaviour to achieve desired societal outcomes.[306]

306 Correspondence from Mundipharma to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, August 2006.

Information and monitoring systems

As consistently indicated in this chapter, ensuring compliance with regulations and guidelines, ensuring Quality Use of Medicines, and enhancing quality practice by prescribers and pharmacists are reliant on establishing and maintaining quality information and monitoring systems. Such information and monitoring systems are in place in Australia, but there are questions as to their comprehensiveness and effectiveness. For example, implementation of the PBS involves gathering information and data on prescribing practices. Based on this information the Professional Services Review Scheme may examine health professionals whose practices have raised concerns. Medical practitioners can register with the Prescription Shopping Program to access patient information that can reduce the risk of pharmaceutical misuse. However, it appears that there are limitations with these current systems.

The critical role of effective information and monitoring systems, and limitations of current systems, has been raised in coronial inquiries into drug-related deaths. For example, in a project reviewing heroin-related overdoses, Professor Olaf Drummer commented that to reduce drug-related harm:

> …there needs to be a system to allow doctors to obtain information on…high-risk cases. This clearly occurs for methadone maintenance programs through a system maintained by the Drugs and Poisons Unit of Human Services. Two options come to mind; one, reschedule all benzodiazepines to Schedule 8, as has occurred for flunitrazepam, or establish a drug monitoring system for drugs of dependence including opioids and benzodiazepines.[307]

Some submissions to this Inquiry expressed a view that there was a critical need to enhance information and monitoring systems. For example, at the public hearings for this Inquiry, Mr Marty from the Pharmacy Board of Victoria stated that:

> One of the serious deficiencies we have in this country is the lack of a medication history database.[308]

Also, in their written submission the Pharmacy Board detailed weaknesses of the current system:

> Those substances included in Schedule 4 or Schedule 8 must be prescribed by an authorised person, usually a medical practitioner, for an individual and specific patient. The assumption is that the prescriber is competent to assess the treatment (medication) needs of all patients.
>
> The treatment is based on a history given by the patient, ie, they have to trust patients. No centralised medication history is available outside of hospitals or within a clinic setting, ie. there are no linked databases of medication history.

307 Victorian State Coroner's Office 2000, *Heroin-related overdose project*, p.107.

308 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, Evidence to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, Public Hearing, Melbourne, 19 June 2006.

> Abusers of prescription drugs usually do not give truthful histories and it is virtually impossible for the prescriber to know the true (medication) history of a patient without an independent real-time record.
>
> Prescribers appear to find it difficult to refuse to prescribe given the current structure of medical practice with allegations of over-servicing for long consultations and complaints from patients, even if there are suspicions of abuse.
>
> It is difficult for state health authorities to identify abusers, as data is not available (apart from Medicare PBS data usually well after the event, and only when a prescription is required to be submitted for payment).
>
> Consequently, many abusers of prescription drugs are likely to have significant problems and exhibit overt 'drug-seeking' behaviour before their abuse is recognised.
>
> Therefore, a major deficiency is identifying not only the problem but also the extent of the problem.[309]

The Pharmacy Board made specific suggestions about the need to enhance current systems:

> This will only be remedied with an online real-time system of medication history being available to authorised persons at the time of prescribing and to pharmacists at the time of dispensing. Coroners have been recommending this option for over ten years.
>
> Health authorities should have access to such a system to ensure accountability of professions in meeting regulatory and professional obligations. Notifications by health practitioners are not always made, resulting in delays in treating some people.
>
> The current permits system under the Drugs, Poisons and Controlled Substances Regulations has the potential to assist with coordination of treatment – but most applications relate to people who do not abuse. Therefore, the majority of red tape (for medical practitioners and government) is an unnecessary burden. An online real-time system would make it easier to identify appropriate treatment at the time of initial consultation and make it less likely that people will commence or, if they have already begun, to be successful, at drug-seeking.[310]

They summarised their submission by noting that one of the most important barriers to quality treatment and reduction of pharmaceutical misuse was:

> The lack of a real-time online medication history database to consult for medication duplication, contra-indications, interactions, unintended dose

309 Submission of the 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 2006.

310 Submission of the 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 2006.

> changes, and "doctor shopping". The data collected by Medicare for the administration of the PBS is seriously deficient in that it only collects information about items actually submitted for payment and it is not examined in a timely manner…[311]

They also suggested the need for:

> A secure electronic prescribing system that can provide for the consumer to determine the pharmacy where they would like to have their prescription dispensed, free of alteration or interdiction, and supplied only on the number of occasions authorized and with patient privacy maintained. This would virtually eliminate prescription fraud, reduce medication misadventure and therefore unnecessary treatment and/or hospitalization…[312]

They recommended that coroners should be consulted about the need for such a database and:

- That prescription stationery be amended to include the indications for use of each medication except where the identification may not assist the patient eg. medications used in some psychiatric conditions eg. "for pain", "for infection".
- That health practitioners with prescribing rights become more accountable for the security of prescription stationery.[313]

Representatives of the Pharmacy Guild of Australia Victorian Branch offered similar statements at the hearings. They observed that there is a problem with current systems of information management and sharing:

> We do have a problem with having a common IT link where we can talk to the general practitioners…where we can pick up these people who are misusing the drugs.[314]

Dr Harcourt, the Chief Health Officer of the Health and Disability Strategy Programs, TAC, commented similarly on the need for coordinated databases to help better manage pharmaceutical medicines.[315]

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311 Submission of the Pharmacy Board of Victoria to the Drug and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

312 Submission of the 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 2006.

313 Submission of the 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 2006.

314 Mr Dipak Sanghvi, President, Pharmacy Guild of Australia Victorian Branch, 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 Hearing, Melbourne, 19 June 2006.

315 Dr Peter Harcourt, Chief Health Officer Health and Disability Strategy Programmes, Transport Accident Commission, 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 Hearing, Melbourne, 19 June 2006.

Demonstrating a strong consistency on this issue, representatives from the PSA stated that:

> We very much support the Commonwealth government's introduction of a real-time medication database.[316]

A recent Victorian project on responding to the misuse of pharmaceuticals[317] indicated that local government has a potential role in monitoring and responding to pharmaceutical misuse. The project report recommended

> That local government monitor medication misuse as part of community safety, substance use or municipal health planning. An analysis of data should make use of:
>
> - Ambulance-attended overdoses; and
> - Hospital admission and emergency presentations.
>
> This data should be discussed with local service providers (including the Division of General Practice) and community members.[318] [319]

Enhanced monitoring and information systems were also requested by people affected by another person's drug use, as indicated by a mother in her comments to the Inquiry:

> These medications need
>
> - a tighter control, either using method of collecting dose daily or in smaller scripts.
> - Better education of prescribing doctors, especially to known or suspected drug users.
> - Computer monitoring of prescriptions.
> - Computer records of who is prescribing...to keep track of doctors who become known as "providers" or legal dealers.
> - Computer records of individuals who have ongoing needs for these drugs.[320]

316 Mr John Ilott, Chief Executive Officer, Pharmaceutical Society of Australia, 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 Hearing, Melbourne, 19 June 2006.

317 Submission from Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

318 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

319 See also the submissions from Ms Lydia Wilson, Chief Executive Officer, Yarra City Council and Ms Sue Morrell, Group Manager, Community Services, City of Melbourne, to the Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, both June 2006.

320 Submission of Ms Margaret Quon, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

Some of those who made submissions to the Inquiry raised concerns about the limited coordination of data and occasionally the poor use of information by key personnel, including coroners.[321] While it is not possible to quantify these concerns, they did reflect a high degree of distress and dissatisfaction with the current systems of information coordination, especially in the event of a drug-related death.

The experience of other jurisdictions

Other jurisdictions have reflected similarly on the importance of building quality information and monitoring systems. For example, to prevent and detect diversion of narcotic drugs, British Columbia in Canada developed a system that has similarities with the suggestions made by the Pharmacy Board of Victoria. Initially called the Triplicate Prescription Program, specially produced prescription pads for narcotics were only issued to authorised physicians and printed on paper that is difficult to fraudulently reproduce. Prescriptions are only valid for a few days. As in Australia, prescriptions have to be written in a way that enhances security (that is, written in words and numbers and carrying a unique identifier of the patient and the prescriber). The physician and the pharmacist kept a copy of the prescription and, during the initial iteration of the Program, an electronic record was created by the Provincial Government.

This system was improved with the introduction of PharmaNet. In this system information is automatically recorded in a central database. The responsible central statutory body can review prescribing profiles of all prescribers and identify risky practices. Data relating to individual patients can also be reviewed, for example identifying those individuals who are 'doctor shopping'. As noted by one reviewer:

> PharmaNet contains the complete known history of drugs prescribed for every resident of British Columbia and, if a visitor to the province requires medication, a record will be created for him/her. At the time of dispensing any drug (not only narcotic drugs), the pharmacist enters the details of the prescription into the PharmaNet database. The previous 14 months' prescribing history for the patient is immediately shown on the pharmacist's computer screen, as is any history of, for example, allergy or adverse drug reaction. The pharmacist is under a professional obligation to consider this information and may, if s/he wishes, seek further details of the patient's prescribing history.
>
> An 'alert' can be attached to the name of a particular prescriber or patient. This warns the pharmacist not to dispense any prescriptions, which may be subsequently presented, issued by the named prescriber or in the name of the named patient.
>
> Every community pharmacy in British Columbia has on-line access to PharmaNet. Access is also now mandatory for every hospital pharmacy and

321 See for example submission from Mr Leon Hain to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, April 2006.

accident and emergency department in the province and it is used in the prison system. On payment of a licence fee, PharmaNet is also accessible to physicians.

Although prescriptions for all drugs, not only narcotics, are entered into PharmaNet, the system makes special provision for the monitoring of narcotics. Each time a prescription for a narcotic drug is entered, an automatic entry is also made in the electronic narcotics log kept by the CPSBC [College of Physicians and Surgeons of British Columbia]. If a physician receives a supply of a narcotic drug for practice use (or office use, as it is called), the supply will be entered into PharmaNet.

The CPSBC has a software program that allows it to analyse PharmaNet data by reference to patients, communities, physicians, groups of physicians or drug types. This flexibility enables the CPSBC to focus on particular prescribing issues. For example, it can keep a watch on individual physicians known to have a history of inappropriate narcotic prescribing. It can isolate high prescribers of a particular drug with a view to identifying outliers [people who prescribe well above the rest of the group] and problem prescribers…The CPSBC can monitor the overall usage (and the usage in a particular area) of specific drugs that are known to have a high value 'on the street'. It can monitor the prescriptions issued to patients known to be addicted to a narcotic. It can identify double scripting patients. It can look out for addicts who might trade one narcotic drug for another (Shipman Report 2005, p.191).

Confidentiality and security of the system are critical:

The College of Pharmacists of British Columbia has prime responsibility for the security of the information in PharmaNet. Only that College and the CPSBC have unfettered access. It has a duty to safeguard patient confidentiality. Information provided for research or Government purposes is anonymised before release[322] (Shipman Report 2005, p.192).

322 Privacy issues, however, could prove a barrier for the implementation of such a system in Australia. For example a representative of the Pharmacy Guild of Australia gave evidence to the Committee relating his misgivings that a comprehensive monitoring system may not be achievable in Australia:

'About 10 years ago now, I was asked to appear as a witness for the Pharmaceutical Society in relation to a death being investigated by the coroner. It turned out that it was the death of a person I had known, because we had dispensed for him from my pharmacy in Collingwood. I think there were seven supposedly expert witnesses: someone from pharmacy, someone from medical practice, someone from the coroner's office, someone from forensic science and so on, and an academic from Melbourne university. She was the last to appear. It was unanimous amongst the first six of us that we could have avoided this with a tracking system – if Michael had not received his medication from 20 pharmacies in five days and if he did not have these massive amounts of drugs that he used to eventually kill himself. I remember the opening line of the academic lawyer who got up at the end. She said, "Well, I'm here to tell you it will never happen, because privacy will never allow this to happen." Here were all these people saying that we could have avoided a death, and probably many deaths, and a lot of malaise in the community – all we need is this little intranet to operate – and the lawyers were saying that it will never happen because there are privacy provisions that we will never overcome.

In British Columbia, with the stroke of a pen, they overcame the problems, but we have never been able to do that. I think most of us would say we could have a huge effect on the abuse of drugs. We could certainly be better in the appropriate provision of drugs through the HIC for bona fide users of all other drugs as well. The privacy provisions, it seems to me, are the great blocker' (Mr Irvine Newton, Pharmaceutical Society of Australia, 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 Hearing, Melbourne, 19 June 2006).

The system appears impressive, and various commentators suggest that it is world's best practice. PharmaNet is apparently valued by medical staff and pharmacists and the system has supported the implementation of a range of quality research into prescribed medicines. A news release from the government of British Columbia stated:

> In 2005, PharmaNet captured 41 million prescriptions at community pharmacies across the province, and generated millions of warning messages about potential medication management issues. PharmaNet detects possible drug-to-drug interactions, ingredient duplication in therapies, fill-too soon and fill-too late warnings (Ministry of Health, British Columbia, Canada, website, 17 May 2006).

However, no systematic review of its effectiveness in reducing pharmaceutical use, while at the same time upholding quality care for those who have 'genuine need', was identified. A report of an Australian trial of a system based on PharmaNet indicated mixed results in the early stages of development (Wrobel 2003). In particular, a significant proportion of medical practices withdrew before or during the trial and there was a low response rate from those who continued. It is also understood that the later iterations of this initial model are still facing significant practical challenges (Wrobel 2003). However, there appears to be widespread and consistent support for investment in such an approach by a number of individuals and organisations that contributed to this Inquiry.

The United States has also invested much effort and resources, across law enforcement and health services, to enhance information and monitoring systems that aim to prevent and detect pharmaceutical drug diversion. The Prescription Abuse Data Synthesis program introduced in the 1980s was associated with

> …a 30 to 70 percent reduction in the use of commonly abused prescription drugs and fewer emergency department visits and deaths attributed to these drugs (National Center on Addiction and Substance Abuse 2005, p.81).

However, it was noted that methodological limitations prevented determination as to whether the decrease occurred in relation to legitimate or inappropriate use of the prescribed drugs. Also, due to lack of resources, the programme ceased at the beginning of the 1990s.

More recently, the Prescription Drug Monitoring Programs have been introduced to accumulate information that could be shared across law enforcement, health services and other regulatory agencies and help identify patterns of use that may be related to pharmaceutical misuse. There is an ongoing debate about the effectiveness of the various United States monitoring systems and the usefulness of the data they accumulate and synthesise (National Center on Addiction and Substance Abuse 2005). In addition to concerns about protecting patient privacy, the value of these systems in reducing pharmaceutical misuse is unclear:

> Determining the effectiveness of PDMPs [Prescription Drug Monitoring Programs] in reducing prescription drug diversion and abuse is difficult since no clear standards or outcomes for measuring effectiveness have been established (National Center on Addiction and Substance Abuse 2005, p.83).

Where there has been a measurable impact, the evidence has not allowed a determination as to whether it has affected the intended target:

> For example, one study of New York's inclusion of benzodiazepines in its triplicate prescription program…found that introduction of that regulation reduced benzodiazepine use by more than 50 percent (compared to no change in use in a comparison state during the period of the study). Although there was some reduction in use among those who may have been abusing the drugs, most reduction was found among non-abusive users…the program reduced use among chronically ill patients for whom the medications were effective (National Center on Addiction and Substance Abuse 2005, p.84).

Also, some researchers proposed that there was some evidence that increases in controls on benzodiazepines were associated with increases in alcohol consumption, as some patients used the latter for self-medication (Fishman et al. 2004). In short, the quality care and wellbeing of patients in 'genuine need' may have been compromised. Subsequently, authorities in the United States have introduced measures that focus on:

> …the abuse of controlled substances and a decrease in diversion without interfering with legitimate access to prescription medications or infringing on patient privacy (National Center on Addiction and Substance Abuse 2005, p.84).

Whether or not these changes have had the desired effect is not yet documented.

What impact does drug scheduling, statutory controls, guidelines and monitoring have?

The regulations and guidelines outlined in the previous section aim to reduce the misuse of medicines. However, they may compromise care for those who are in 'genuine need' and increase costs for providing care to this latter group of patients. Such patients include those who do not abuse other drugs, but who may be mistakenly suspected of drug-seeking behaviour and those patients who are drug-dependent, but who have a genuine need to access a medication – for example, they may require pain management due to some acute need, such as an injury. Thus medical practitioners need to develop and maintain skills not just in identifying drug-seeking behaviour but also in identifying those in 'genuine need' (eg. see White & Taverner 1997).

As already mentioned, this is a challenging balancing act. In the United States one review described the tension this creates:

> The scrutiny of professional boards and monitoring programs such as PDMPs [Prescription Drug Monitoring Programs] has, in some cases, created a fear that legal actions will be taken against physicians and pharmacists regarding their prescribing and dispensing practices. As a result, practitioners may under-treat patients or use less appropriate medications that are not covered by a monitoring program (National Center on Addiction and Substance Abuse 2005, p.86).

The potential unintended impact on patients in 'genuine need' is captured by comments from one United States physician:

> If you think for one second that I've worked this hard to get where I am to risk it by writing prescriptions for chronic pain, you'd better think again (National Center on Addiction and Substance Abuse 2005, p.86).

There is concern that while pharmaceutical misuse can create harm, under-treatment also creates risks. For example, under-treatment of pain can lead to health problems and, paradoxically, contribute to alcohol and drug abuse as a person attempts to self-medicate (National Center on Addiction and Substance Abuse 2005).

Restricting or controlling medicines with high misuse potential by rescheduling them to less accessible categories may, at first glance, appear to be a logical and straightforward action that will reduce misuse. However, such procedures are not without contention, and there may be costs and other unintended consequences. For example, in the United States, attempts to control the misuse of hydrocodone compounds (a group of narcotic analgesics) by rescheduling this widely prescribed medicine has resulted in some concerns:

> Opponents to rescheduling hydrocodone argue that it will make the drug less accessible to patients because they will be required to visit their physician more frequently to obtain a new prescription rather than simply refilling their existing prescription. They argue that doctors will be overloaded with patient visits, increasing pain-related healthcare costs (National Center on Addiction and Substance Abuse 2005, p.77).

An Australian discussion paper proposed that drugs of concern could be designated 'authority-required prescriptions' (Dobbin 2001). The author cited examples from other countries where, in an attempt to reduce the misuse of temazepam capsules, such restrictions have been imposed, reducing the number of prescriptions. Indeed, as discussed in Chapter 4, subsequently in Australia the PBS Schedule was adjusted in exactly this manner, specifically because of concerns about the rising incidence of harms that arose from the unlawful and unintended use of temazepam capsules for injection. Controls were implemented so that, from May 2002, temazepam 10mg capsules in a 25-pack were designated as 'authority-required prescriptions'. The change in practice was accompanied by the provision of information on the rationale of the initiative to both medical practitioners and pharmacists:

> On 1 May 2002, temazepam 10mg capsules (25 capsule pack size) will become an 'authority required' pharmaceutical benefit.
>
> Its new listing comes with a cautionary note for doctors that significant adverse health outcomes are associated with injecting temazepam in capsule form, and that wherever possible, tablets should be prescribed in preference to capsules…
>
> Doctors will need to confirm capsules are being prescribed to manage insomnia in an individual who has not responded to treatment for this condition in the tablet form…
>
> The Pharmaceutical Benefits Advisory Committee (PBAC) recommended this higher listing following advice from the Australian Pharmaceutical Advisory Council that the intravenous use of temazepam capsules was increasing due to a heroin shortage (Health Insurance Commission 2004, p.1).

The rationale for such a strategy was that this could result in pressure to prescribe other benzodiazepines or tablets, thereby potentially decreasing the highly risky use of capsules and potentially limiting diversion and misuse. On the other hand, the Pharmacy Board of Victoria was concerned that such changes could potentially create demand in other areas. Commenting on the apparent increase in drug-seeking patients targeting 20mg temazepam capsules, the Pharmacy Board commented:

> It is also thought that the absence of 20mg temazepam tablets and the fact that this medication is not a PBS item may have contributed to this success as the drug-seeking patient does not need to emphasise the need for the capsule formulation and can more readily request a larger dose than usual quantity on the basis of economy (Pharmacy Board of Victoria 2003, p.7).

Nevertheless, the change in practice in Australia *did* result in a net reduction in the prescription of capsules under the PBS – from 185,404 prescriptions a month in January 2001 to 1,859 prescriptions a month in November 2003. In 2004 the pharmaceutical producers withdrew temazepam capsules from the Australian market because of concern about the abuse potential (Dobbin 2006a, unpublished).

The City of Melbourne gave a local example of the impact of this change in practice:

> According to workers based at Living Room, the use of injecting gel capsules by their clients has dramatically declined and is now virtually non-existent since the Federal Government withdrew Temazepam gel-based capsules from the Pharmaceutical Benefits Scheme.
>
> Furthermore, the advocacy carried out by the Victorian Department of Human Services Drugs policy unit around the harms associated with Temazepam gel-based capsules has seen pharmaceutical companies and manufacturers withdraw gel capsules from the Australian market.[323]

323 Submission of the City of Melbourne to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

Similarly, concern about widespread misuse of flunitrazepam (for example, Rohypnol) resulted in the National Drugs and Poisons Schedule Committee (NDPSC) rescheduling the medicine in 1998, from a Schedule 4 to a Schedule 8 medication, resulting in a decrease in accessibility and use of the drug (Australian Illicit Drug Report 1997–98). A representative of the pharmaceutical industry who was involved in the NDPSC process for rescheduling flunitrazepam indicated to the Committee that both the general process of rescheduling drugs and the specific action of rescheduling flunitrazepam was neither straightforward nor would it necessarily result in unequivocal benefits:

> [o]ver the course of the discussion around the flunitrazepam rescheduling…the committee [NDPSC] came to accept the evidence that we [Roche Australia] put before it that there was no evidence that flunitrazepam, which is more commonly known as Rohypnol, was more addictive that any other benzodiazepine…The committee did come to accept this, and they then had a choice of things that they could do. They could either not reschedule flunitrazepam to schedule 8 on the basis that it was not different to any other benzodiazepine or they could continue to reschedule it to schedule 8 and leave the others in schedule 4 or, as we proposed, they could decide to reschedule all benzodiazepines into schedule 8…but the difficulties of dealing with benzodiazepines and their legitimate medical uses probably was the reason that the committee did not decide…to do that…
>
> You might ask yourselves what has happened since then [the rescheduling of the drug and the discontinuance of producing and marketing Rohypnol by Roche]. There has been transference of the preferred agent for misuse, both in the polydrug user situation and in the date rape situation…the misuse has been transferred to another Roche benzodiazepine, which is Rivotril. That is the brand name, and its generic or active substance name is clonazepam. It is very similar in appearance to the old Rohypnol two-milligram tablets, but Rivotril is used for the treatment of epilepsy.[324]

A number of submissions to this Inquiry made the point that while the scheduling system overall was flexible and worked relatively well, it was thought that on occasion some drugs had been wrongly placed in an inappropriate schedule. For example, a submission from a group of clinicians working in the Victorian public hospital sector noted that alprazolam (Xanax®), a benzodiazepine with a particularly high potency, short onset and short duration of action, is only listed at Schedule 4 despite the concerns of many clinicians:

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324 Ms Susan Alexander, Head of Regulatory Affairs and Head of Operations, Roche Products on behalf of Medicines Australia, in conversation with the Drugs and Crime Prevention Committee (via telephone), 20 July 2006. It should be noted that Ms Alexander was speaking primarily in her role as a representative of Medicines Australia, the peak industry body for pharmaceutical companies in Australia.

> 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.[325]

Some submissions have gone further and argued that most if not all benzodiazepines should be subject to Schedule 8 controls and/or a permit or authority system currently applicable to other drugs of addiction.[326]

While not voicing opposition to such strategies, the submission of the AMA drew attention to the lack of evidence of the effectiveness of such approaches:

> …we accept that on occasions, such as the rescheduling of some benzodiazepines (fluntirazepam), and change in PBS prescription requirements (temazepam capsules), it is justifiable on public health and public safety grounds for this to occur. However, I note that on published evidence (Breen et al MJA 2004; 181(*6*): 300-304) a significant positive outcome has yet to be realised.[327]

The above discussion is not intended to support an argument against controls and other responses that aim to reduce access to medicines that are being misused. Rather, it highlights the need to base decisions on available evidence, to invest in developing evidence where this is currently insufficient, and to monitor carefully the impact of any regulations or changes in procedures, adjusting them as indicated.

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325 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.

326 See for example, submission of Salvation Army Crisis Services to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, April 2006. On the other hand, the Pharmaceutical Society of Australia 'remains unconvinced' that the rescheduling of large packets of pseudoephedrine to Schedule 4 will stem the illicit diversion and trade in this substance in the long term. Other measures such as Project Stop in their view has better potential to address this issue. See submission of the Pharmaceutical Society of Australia (Victorian Branch) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

327 Submission of the Australian Medical Association to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

Conclusion

This chapter has outlined the roles and functions of various statutory and professional bodies. It is evident that in Australia, as in other countries, the risk of prescription medicine diversion and misuse has been recognised and a range of responses have been developed. Regulatory processes have been established to ensure quality use of medicines in general and to reduce the risk of diversion and misuse in particular. State and territory statutory bodies have developed procedures to reduce a range of risks from 'drugs of dependence' and professional boards and groups have produced guidelines that support such aims.

This brief review suggests that such procedures are consistent with international practice and, in general, procedures and guidelines have been comprehensively developed using credible processes and involving key stakeholders. However, the evidence base to assess the effectiveness of these strategies is limited. This is a concern for two reasons. First, it limits the ability to direct investment to those strategies that are cost-efficient and away from those that are ineffective. Second, there is some concern that strategies may have unintended impact on patients who have 'genuine need' and whose care may be compromised.

These approaches all rely on quality information and monitoring systems. There is currently insufficient information available that can inform the Committee as to whether these systems can be improved. It is, however, important to note that other countries are reviewing and attempting to improve their systems. This chapter has focussed very much on the health services. As noted in this Inquiry, pharmaceutical diversion and misuse has relevance for health and other groups such as law enforcement. Lessons from overseas, and local reviews, suggest that it may be appropriate to review the information and monitoring systems in concert with developing a coordinated intelligence system that can guide practice across the various systems, while at the same time ensuring patient care and patient confidentiality are not compromised.

Finally, although various statutory bodies and professional groups have responsibilities to review the context and nature of professional practice, no evidence was found on the effectiveness of these initiatives. It may be timely to review the adequacy of such procedures and in particular assess whether adequate resources are allocated to ensure effective implementation of compliance strategies.

Questions for further consideration

Is there a case to review the scheduling of some drugs, particularly for some of or all of the benzodiazepines?

Is there a need to include assessment of abuse potential of new formulations of pharmaceutical drugs?

What re-formulations of drugs are most likely to reduce abuse potential?

What skills do health care staff need, and what is necessary to help them implement quality responses to pharmaceutical misuse?

What compliance strategies are the most effective and what resources will ensure they are implemented effectively?

What are the best models and systems of coordination that can be applied across sectors (for example, law enforcement and health)?

What information and monitoring systems will produce the best outcomes, while maintaining quality care for patients in 'genuine need'?

8. Information, Education and Harm Reduction

Effective responses to prevent and reduce pharmaceutical misuse will involve activity in various domains. Legislation and regulation clearly have a role and, as will be discussed in Chapter 9, it is important to review treatment responses. This chapter, however, will focus on the requirement to provide information and education, ensuring the provision of effective harm reduction strategies and developing and delivering education and training to staff who have a role in responding to pharmaceutical misuse. In particular, there are likely to be distinct needs for groups such as:

- the broad community;
- health care and other professionals; and
- people who are misusing pharmaceutical drugs.

General information provision and education

Evidence provided to the Inquiry indicated that there was a need to provide information and education for a number of target groups. It appears that, in the broad community, within the health professions and among drug using groups, understanding of the risks associated with pharmaceutical drug misuse is variable. For example, the organisation Anex explained the need for improvement in information and education provision.

> Anecdotal evidence suggests that despite the removal of temazepam [gel caps] … clients accessing NSPs [needle and syringe programmes] are continuing to inject pills including a variety of benzodiazepines and other pharmaceuticals. Clients are presenting with a variety of physical harms including vein damage, infection and associated health problems. It is clear that further information and education is required to ensure safe injecting practices to minimise such harms…
>
> We know that injecting drug users have very variable understandings of the risks they are undertaking. We also know that Needle and Syringe Program staff and other health professionals working on a day-to-day basis with people who inject drugs have very variable knowledge. It seems from the Anex perspective that

> there is a need for sophisticated and highly targeted research to investigate those two questions, being service provider skills and knowledge, as well as injecting drug user skills and knowledge.[328]

Submissions from local government also suggested there was a need for information and education programmes in response to low levels of knowledge with regard to prescription drug abuse:

> Local service providers including Living Room, Next Door and Health Works Primary Health[329] have reported an increase in the number of clients, known to be using benzodiazepines in large quantities, presenting with erratic and violent behaviour.
>
> These same clients are also showing signs of and/or involvement in:
>
> - Poor injecting practices that increase the risk of Hepatitis C and HIV transmission;
> - Lack of safe sex practices leading to possible infection of sexually transmitted diseases; and
> - Increased likelihood of overdose due to poly drug use.[330]

There were also suggestions that some specific at-risk groups, such as prisoners, had a particular need for information and education:

> Prisoners requesting benzodiazepines should be educated on the indications, risks and benefits of these drugs, including the risk of dependency. This has been shown to be effective in reducing use amongst patients in the community.[331]

Information with regard to prescription drugs

Notwithstanding the gaps in information with regard to prescription drugs for specific groups in the community, there are some sources of information and education programmes available. This information is provided by a number of organisations, including health services, needle and syringe programmes, individual medical staff and pharmacies, peak agencies (such as the Pharmacy Services Association) and pharmaceutical companies.[332] The various sources of information include:

328 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

329 These are Melbourne based health services.

330 Submission of City of Melbourne to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

331 Submission of Mr Michael Burt, Chief Executive Officer, Victorian Institute of Forensic Mental Health to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

332 For example, see correspondence from Mundipharma, August 2006, and comments of Ms Susan Alexander, Head of Regulatory Affairs and Head of Operations, Roche Products on behalf of Medicines Australia, in conversation with the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

- The Australian Drug Information Network (ADIN), which is managed by the Australian Drug Foundation (ADF). It provides access to information about drug use, drug effects, harm reduction and treatment options and has links to a range of international websites;
- Direct Line, which is a Victorian service, providing advice and information to medical staff about safe and effective management of drug problems and, as noted by Dr McDonough, this service has now been adopted in other jurisdictions,[333] and
- Internationally, there are services such as Erowid, which is

> …a member-supported organization providing access to reliable, non-judgmental information about psychoactive plants and chemicals and related issues. We work with academic, medical, and experiential experts to develop and publish new resources, as well as to improve and increase access to already existing resources. We also strive to ensure that these resources are maintained and preserved as a historical record for the future.[334]

The following discussion outlines the information available with regard to the safe use of medicines, the risks of pharmaceutical misuse and the services available to address these issues.

Information about safe use of medicines

Clearly, even people who have a legitimate reason to use prescription or indeed over-the-counter medicines need comprehensive and up to date information with regard to the drugs they have purchased or been prescribed.

To a certain extent the requirement for such information is mandated by Commonwealth regulation.[335] Since 2003, prescription medicines and pharmacist supplied, or Schedule 3 products, are required to have a Consumer Medicine Information (CMI) document supplied with the medicine.[336]

Hirshorn and Monk state that 'enormous effort has been invested in CMI development in Australia with the aim of producing highly useful and usable information for consumers' (2006, p.667). They continue:

> Guidelines called 'Writing about medicines for people' (the usability guidelines) are in their second edition, providing guidance for sponsors on how to prepare CMIs with highly consistent usability. Unlike the European Union, Australian sponsors are not required to provide the CMI as a pack insert but may distribute the documents in a form that enables the CMI to be given to a person to whom a product is administered or dispensed. A system has been developed for

333 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 20 June 2006.

334 Erowid website at: http://www.erowid.org/general/about/about.shtml

335 See also the discussion in Chapter 6 of this Interim Report.

336 See Section 9A and Schedule 12 of the Therapeutic Goods Regulations 1990.

> electronic distribution of CMIs, so that they may be printed by doctors or pharmacists from their computer software (Hirshorn & Monk 2006, p.667).

In addition to the compulsory CMIs, there have also been voluntary initiatives promoted by health care professionals. For example, the Pharmacy Society of Australia has developed a series of fact cards, through the Pharmacy Self Care programme, that aim to promote safe and effective use of medicines. This health information is intended to support the counselling and advice services that many pharmacies provide (see Pharmacy Society of Australia website). The Fact Cards are reviewed and, where appropriate, updated on an annual basis so currency is maintained. They are made available in pharmacies so that patients can self-select, but may also be provided with advice and counselling from the pharmacist. There are 14 categories of information that include over 80 titles. Of particular relevance to this Inquiry is that they cover subjects such as 'Wise use of medicines', 'Methadone', and 'Drug overdose and safer injecting practices'. No information was provided on the proportion of pharmacies that stock and supply these resources. An example of the information provided on a fact card is given below:

> **Medicines and driving**
>
> Some medicines can affect your ability to drive, cycle or use machinery. You need to be alert and be able to respond quickly to changes in your environment when doing these tasks. Not everyone is affected to the same extent and different people are affected by medicines in different ways. The danger is you may not notice the effect a medicine has on you, until it is too late. When starting a new medicine, always ask your pharmacist if it's safe to drive, cycle or use machinery and what the warning signs are to look for. If it's not safe, DON'T DRIVE (Pharmacy Society of Australia 2006, 'Self-Help DR-7 2000').

Requirements such as CMIs and voluntary initiatives by pharmacists are a valuable, indeed essential, aspect of information provision with regard to prescription medicines. Unfortunately, however, it is unlikely they will be read or accessed by people who acquire their drugs in illegitimate ways, for example through street trade. It is crucial, therefore that there are alternative means by which such users of prescription drugs receive information with regard to the risks associated with the use and misuse of prescription drugs.

Information about the risks of pharmaceutical misuse

One way in which information can be accessed by people who may not receive their medicines through legitimate sources is from health and alcohol and drug services. Some health services provide information specifically to people who misuse drugs. For example, the Western Region Health Centre described their role in providing information and education. They identified that among other issues that contributed to the risks of pharmaceutical misuse, a lack of awareness about benzodiazepines was of concern. Issues they specifically identified were:

- lack of awareness about risk associated with 'benzos' and dependency
- lack of awareness about effects of 'benzos'
- lack of awareness about interactions between 'benzos' and opiates.[337]

They also described the strategies they employed to respond to these gaps in knowledge:

- Service users presenting for referrals for benzodiazepines are provided with harm reduction information about safer benzodiazepine use, the risks of dependency and are offered support if they think they are dependent.
- A health promotion campaign was developed in response to the current patterns of drug use and drug availability by Health Works' service users. The workshops were written to increase user's awareness of benzodiazepine effects and ways for reducing associated risks. As part of the campaign, users were engaged in our needle and syringe program for one-on-one education and peer education workshops were held. Health Works recognised the importance of developing and providing this new education workshop to its service users and found within current systems the capacity to employ a worker to write and deliver the workshop. Due to budgetary limitations, Health Works was restricted to the delivery of only 12 workshops throughout the month of March. During this period, 71 Health Works' service users were educated on the harms associated with benzodiazepine use.[338]

Some other non-government organisations have also developed services and resources to address prescription drug abuse. For example TRANX (Tranquilliser Recovery and New Existence) informed the Committee of resources they had developed to help improve relaxation, enhance sleep, and the provision of information sheets on topics such as safe medication use. Ms Gwenda Cannard from TRANX suggested that there was a requirement not only to invest in information and education about pharmaceutical drug misuse but also to encourage the use of alternatives to such medications by promoting services such as those that help manage anxiety and sleep disorders. The agency suggested there was a need for:

- Continued community education relating to sleep strategies without drugs and evidence based options for anxiety disorders treatment…
- Continued community education…with reference to people from culturally diverse backgrounds delivered in their first language…

337 Submission of Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

338 Submission of Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

- [Support for] Services providing counselling for anxiety disorders to promote their service more effectively.[339]

In undertaking the research for this Inquiry, it became apparent that there were gaps in information provision. While it proved to be relatively straightforward to access websites that provided quality information about benzodiazepines and the use of methadone, buprenorhpine and naltrexone for the treatment of opioid dependence,[340] for example the ADIN website, it was much more difficult to access information about the misuse of narcotic analgesics. Indeed, web searches for narcotic analgesics and/or opioids generally resulted in access to information about methadone and buprenorphine maintenance treatment and websites devoted to narcotic analgesics and pain management. Given the level of use and harms associated with narcotic analgesic misuse, especially in illicit drug using populations (see Chapter 3), this is, perhaps, an omission that should be remedied.

Information about services

It has become evident to the Committee that not only is there a need for information with regard to prescription drugs and their effects, consumers of these drugs also require information with regard to the services that are available to address the use and, more importantly, abuse of these drugs.

Community sector websites, such as the ADIN, which is managed by the ADF,[341] provide information about services and where to get further information and advice. There are also government services that can provide valuable information with regard to prescription drug abuse. For example, the Drugs Policy and Services Branch, Rural and Regional Health and Aged Care Services Division (Department of Human Services (DHS) Victoria) produced the booklet, *Drugs: How and where to get help* (2002). The directory provides information about how to find out more about drugs, how to get help and how to access drug treatment and counselling services. While these are largely broad-based drug services they have relevance for people who abuse pharmaceutical drugs, and indeed the directory does specifically identify a number of these medicines.

Targeting information appropriately

Notwithstanding any gaps in delivery, the submission from Anex, peak support body for injecting drug users, drew attention to the fact that there are various

339 Submission of Ms Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

340 See Chapters 2 and 9 of this Interim Report.

341 See the submission of the Australian Drug Foundation to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006. Information from this website regarding drug effects and treatment is provided in Chapters 2 and 9.

information and education programmes that have been conducted with injecting drug users. Anex explained why such programmes were important:

> Various educational programs have been conducted in a variety of locations to raise awareness and understanding of the risk factors for opiate overdose (Loxley et al 2004). Indeed, as Dietze et al (2005) note, 'overdose prevention has become a major focus of heath promotion messages aimed at the heroin-using population' (Dietze et al 2005, p.636). The Dietze et al study supports previous findings that the consumption of benzodiazepines and other CNS [central nervous system] depressants are associated with increased risk of overdose; the authors concluded that further research is needed to determine the risk associated with various quantities and frequencies or use of these drugs for overdose (Dietze et al 2005).
>
> However, they note that little formal evaluation of their impact is available. Anecdotal evidence suggests that whilst there is awareness by some users of the general risks around poly-drug use and the specific risks associated with mixing benzodiazepines and heroin, users (and indeed many service providers) are not knowledgeable about the half-lives of these drugs. A drug's half-life refers to the time it takes for the blood concentration to fall to half its peak value after a single dose. This time may vary significantly between individuals. Benzodiazepine half-lives can be very-short acting, short acting, medium acting and long acting…
>
> Anex believes this is an area that requires further consideration. Practitioner feedback indicates that while some individual drug users may have a degree of knowledge about the half-lives of various benzodiazepines and other pharmaceutical drugs, many are unaware of these risks…
>
> Converting complicated information on the half-lives of a variety of benzodiazepines into simple, accurate and effective health promotion material and information that can then be provided to current injectors accessing an NSP is a difficult task. Many services lack the capacity to meaningfully engage with clients on such a complicated issue. However, this may be further compounded by a lack of knowledge on the part of some service providers.[342]

A lack of evaluation?

The above comments by Anex highlight a dilemma regarding the development and implementation of information and education strategies. As discussed above, a number of submissions indicated that there seems to be variable knowledge about the risks of drug use in general and in particular in relation to benzodiazepines and other pharmaceutical drugs. As noted in Anex's submission, there has been little formal evaluation of previous programmes, resulting in very limited evidence that can guide practice. This weakness is not unique to responses to pharmaceutical misuse. For example, in a major review

342 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

of responses to drug problems in general, Loxley, Toumbourou, Stockwell, Haines et al. (2004) noted that there is a lack of compelling evidence that can inform the development and implementation of quality community information and education initiatives. Rehm, Babor & Room (2006) reached a similar conclusion about education and persuasion initiatives that were aimed at reducing alcohol-related harm. More directly relevant to preventing pharmaceutical misuse, a review of various information and education strategies in the United States concluded that unfortunately:

> No formal independent evaluations of the effectiveness of these programs in preventing prescription drug abuse are available (National Center on Addiction and Substance Abuse (CASA) 2005, p.95).

Limited evidence, however, should not be an invitation to inertia. It should prompt the development of more systematic evaluation of activities and a review of health promotion and communication literature to ensure the highest quality approaches are supported. Many people who made submissions to this Inquiry argued that there was a need for more investment in providing quality information and education.[343] A similar conclusion was reached in the United States, where it was recommended that:

- Government-sponsored public awareness campaigns that focus on alcohol, marijuana and other illicit drugs should include the abuse of controlled prescription drugs as well as the dangers of poly-substance abuse.
- Government-sponsored public awareness campaigns should inform parents to safeguard their prescription drugs from their children, and advise individuals and families to dispose properly of unused and controlled medications.
- Schools and communities should incorporate prescription drug abuse…into evidence-based substance use prevention programs (CASA, 2005, pp.102–103).

Submissions to the Inquiry expressed concern that there is a high degree of ignorance about the nature and effects of prescription drugs, and that there is variable knowledge about the risks associated with misuse. While a variety of organisations do provide information and education in the form of websites, hard copy information or advice to individual patients/clients, there does not seem to be any systematic approach to identifying what information and education is needed. Nor was evidence found that indicated the development and delivery of these strategies is coordinated, and unfortunately there is, moreover, little evidence to guide the development and implementation of effective practice.

343 See for example, submission of Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

Education and training for health professionals

> It is so important that doctors are trained on how to help addicted people, not just cover up their problems with more drugs. Helping addicts was not on the agenda 10, 20 years ago but it is now, and doctors must have extra training to know when to seek psychological help for their patients. Because of a doctor who sought extra training in order to help addicts, my child has recovered and is now a professional and a different person.
>
> I felt betrayed and disillusioned by the first doctor I took my child to because of his lack of training to help addicts withdraw from illicit drugs. I thank God for the second doctor, his training, his support and the knowledge to refer my child on to a psychiatrist when he felt he was out of his depth.[344]

Several submissions to the Inquiry indicated that there was wide variation in the knowledge, skill level and willingness of health professionals to effectively address pharmaceutical misuse. This is despite the fact that, as described in Chapter 7, many professional boards and professional bodies have developed clinical and practice guidelines. Some also conduct training programmes for their members. Unfortunately, the reach of these programmes appears to be limited. For example, in the United States it has been reported that a minority of medical staff receive instruction in identifying and controlling prescription drug diversion. The National Center on Addiction and Substance Abuse (CASA) at Columbia University stated that few medical practitioners and pharmacists receive instruction in identifying addiction, especially to prescription drugs, and that even when they do receive such training, it is usually only for a few hours. They were apparently ill equipped to understand the laws governing prescription drug controls and were unsure what to do to conform with these:

> Less than a third of physicians believe that federal (31.0 percent) and state (30.3 percent) laws are "very or somewhat" clear and six in 10 pharmacists believe that federal (59.0 percent) and state (62.4 percent) laws are "very or somewhat" clear on what actions they should take if they believe a patient is diverting or abusing controlled prescription drugs (CASA 2005, p.91).

Physicians were also not particularly skilled at identifying pharmaceutical dependence. Describing an earlier investigation, CASA observed that:

> …physicians were presented with a hypothetical case of a 68-year old female patient with symptoms consistent with alcohol or prescription drug abuse and asked to offer five possible diagnoses. In this case, only one percent of the physicians surveyed offered substance abuse as a possible diagnosis (CASA 2005, p.92).

344 Submission of a 'Concerned Mother' to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006. The name of the person making the submission has been changed to protect her anonymity.

The American study also reported that physicians even found it difficult to discuss pharmaceutical misuse with their patients, leading to poor prescribing practices.

In Australia, it has been argued that a significant proportion of health care staff does not provide optimal care to people who are drug dependent. Turning Point Alcohol and Drug Centre, for example, commented that:

> A major concern in the community setting is that some unskilled (in the sense of drug and alcohol treatment) General Practitioners inappropriately prescribe benzodiazepines to alcohol and drug treatment seeking clients by 'rubber-stamping' requests. Possibly the best response to these clients is that practitioners uniformly offer to engage them in a treatment program where they receive safe daily amounts of the drug they are dependent on and where this is tied to them attending for regular appointments. This referral process, however, often does not occur because practitioners are not equipped with the information skills to handle such clients. An additional problem is that treatment-presenting clients are sometimes not actually interested in treatment and become antagonistic when practitioners do not give them what they want the way they want it (i.e. prescription drugs). In this context there is an ongoing need for alcohol and drug treatment modalities to be entrenched in medical curricula, alcohol and drug information materials to be readily available to community prescribers (and pharmacies), and for referral information to be available in community treatment settings (e.g. general practices).[345]

Anex has also observed that that some GPs might suddenly cease prescribing benzodiazepines, risking fits and seizures, rather than embarking on a considered and evidence-based withdrawal programme. One service provider cited by Anex said:

> More often people present to [the] service in acute benzodiazepine withdrawal as their GP refuses to provide any more scripts because their use is so high. This is medically quite dangerous and requires immediate medical attention.[346]

Poor engagement and reluctance to intervene might occur due to a variety of reasons, as suggested by Allsop and Helfgott:

> Responses may not be consistent with the practitioners' beliefs and values. Organizations may not have relevant policies, funding contracts or performance indicators, or the available resources…(This can include)…lack of knowledge and skills, limited opportunities to develop skills, lack of incentives and…overstretched staff lacking time and enthusiasm to adopt new ways of working…Personal factors can include attitudes about drug use and the all too

345 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

346 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

> common marginalisation of people affected by drugs…Subjective experience and opinion may compromise objective and compassionate consideration of the individual client's needs (Allsop & Helfgott 2002, p.217).

Until recently, education and training of Australian health professionals has been distinguished by the near absence of 'drug education' from mainstream health curricula (for example, see Allsop & Helfgott 2002; Roche 1998). This has been an almost universal comment made with regard to every inquiry conducted by the Drugs and Crime Prevention Committee. In addition, while some submissions to this Inquiry described programmes delivered by their own or another agency, they generally noted that such programmes had limited resources and that there was a requirement for increased investment in and coordination of such programmes.[347] In short, it was generally reported that there was an urgent need to enhance professional education and training to increase the probability of medical practitioners and pharmacists providing quality patient education, recognising and managing drug-seeking behaviour, managing dependence and withdrawal and providing harm reduction information.[348]

In summary, it appears that there is a substantial need for education, training and other workforce development strategies for health professionals. The nature and content of such training will be examined in more detail in Chapter 9. However, as with 'information and education' health promotion activities, it does appear that while there is a range of programmes being developed and implemented by a variety of organisations, there is no evidence of coordinated effort, and to some extent the rather voluntary nature of much of the education has resulted in limited penetration into the health professions. Dr Nick Carr, a highly respected general practitioner and medical educator/trainer, identified the need for such coordinated effort:

> It has long been my view that GPs are not given clear enough advice and instruction about how to deal with doctor shoppers. This is partly because "experts" have not always agreed on the appropriate approach. I would like to see a state/national programme of workshops for GPs on how to manage this problem, but only if the content of such workshops was clearly agreed on in

347 For example organisations such as TRANX and Anex provided eduction and training programs – however, the resources for such programs were modest. TRANX also highlighted the training provided by Dr Nick Carr as being particularly useful in preventing and reducing pharmaceutical misuse. See the submissions from Ms Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006, and Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

348 See for example evidence from Public Hearings given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, from: Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 20 June 2006; Anex, 20 June 2006; and TRANX, 19 June 2006.

> advance and did not just reiterate the somewhat woolly advice that has often circulated previously.[349]

It is likely that such investment will be valuable – skilled clinical staff can have a dramatic and positive impact, as illustrated at the beginning of this section. It also needs to be stated, however, that while better training for health care professionals clearly must be provided in the area of prescription drug abuse, this is not akin to attributing 'blame' to these professionals, particularly prescribing doctors, for any shortcomings of the system. Many people who gave evidence to the Committee observed that doctors and other staff were under enormous pressures and constraints that impacted upon their ability to always provide a 'best practice' service. For example, Dr Matthew Frei of the Interhospital Group gave the following evidence to the Committee:

> There is a lot of pressure on GPs…I would not criticise GPs because their job is extraordinarily difficult.[350]

Mr Steve Marty, Registrar of the Pharmacy Board, expressed a similarly understanding attitude to the constraints and problems faced by prescribing doctors:

> When medical practitioners prescribe, of course, they are relying on a truthful history being presented by the patient and, to a certain degree, you have to accept it unless you want to be in an argument or accuse the person of lying or interrogate them further. So they do need to have very good diagnostic skills, but these people also are very skilled in the way that they present information: they will have done their research, know what to say; they will know all of the symptoms sometimes better than some of the practitioners involved, I suspect. … GPs come under pressure, certainly from aggressive behaviour, threats to them or to patients waiting in the reception area. There have been occasions where friends have caused substantial trouble in the waiting areas and all the GP wants to do is get them out of the surgery, so they will write a prescription.[351]

While the discussion in this chapter has generally described the needs of needle and syringe programme providers and other health professionals, such as medical practitioners and pharmacists, it is likely that other professions should be considered in more detail, given the harms associated with pharmaceutical misuse. For example, what are the education and training needs of emergency services staff, police, or welfare organisations? It is sometimes assumed, for instance, that because a person may work in the alcohol and drug sector that

349 Submission of Dr Nick Carr to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

350 Dr Matthew Frei, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

351 Mr Steve Marty, Registrar, Pharmacy Board of Victoria, 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 Hearing, Melbourne, 19 June 2006.

they automatically have the knowledge to equip them to give advice with regard to the drug in question. While this may be true of some or even most drugs that alcohol and drug workers focus upon, evidence to this Committee suggests that this will not always be the case with regard to prescription drugs. For example, John Ryan of Anex told the Committee that in relation to benzodiazepines:

> One of the most obvious areas of lack of knowledge is around benzodiazepine half-lives. People assume that, if they pop a pill today, [there will be no lasting effects tomorrow], whereas in fact the half-lives of a lot of benzodiazepines are much more significant and, in fact, can go up to several days, in which case people are at significant risk of overdose a long time after they think that their benzo use is no longer relevant. That sort of information is not well understood by people who use drugs. It is also not well understood by people who are providing services to people who use drugs, and I think that would especially include the Needle and Syringe Program because of the volunteer nature of many of those services.[352]

A former abuser of prescription drugs made similar comments when she gave evidence to the Committee. She related her experience of seeking advice from one of the main telephone drug advice agencies in the following terms. Again stressing that often the volunteer nature of these services meant that sometimes those who staffed them were insufficiently trained:

> If you are lucky you [can access] one or two 24-hour helplines. I have rung those a couple of times...These are the drug helplines and they are [staffed by] young people. They are kids. They have not got a clue what you are talking about because they are there for the illicit drugs more than anything else. You think, 'You've got to be joking' and that is it.[353]

One final point with regard to the education and training needs of those who may come in contact with prescription drug abusers concerns the role of local government. Local governments provide services to individuals who misuse these drugs. Questions are raised about the training of their staff who deliver such services, for example: What education and training needs might such groups have? Does the aggression that is associated with pharmaceutical misuse (see Chapter 4) create particular training needs for staff who come into contact with such clients?[354] Unfortunately, there was little evidence in the literature, or

352 Mr John Ryan, Chief Executive Officer, Anex, 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 Hearing, Melbourne, 20 June 2006.

For a more detailed description of what is meant by a drug's 'half-life', see Chapter 2 and glossary in Appendix 3.

353 'Mary', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

354 For example, see the submission of Melbourne City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

direct evidence from people consulted in the Inquiry, to answer such questions. Such questions, therefore, require further consideration by the Committee.

Harm reduction

What is harm reduction?

The concept of 'harm reduction', in its current form, emerged in the early 1980s, substantively driven by the observation that sharing injecting equipment played a major role in the transmission of HIV and the subsequent AIDS epidemic. While closely associated with needle and syringe programmes, harm reduction is not restricted to such activities. As Loxley and her colleagues explained:

> Harm reduction is often thought of only as needle and syringe programs, but many more strategies are used and, in many cases, have been shown to be effective (Loxley, Toumbourou, Stockwell, Haines et al. 2004, p.236).

Effective harm reduction strategies are generally designed to focus on the broad context of drug use, such as the mode of use, context of use and preventing harm to others (for example, members of an individual's family or the broad community). While there has historically been much debate about what is and what is not harm reduction, some useful and practical definitions are available.[355] The International Harm Reduction Association has defined harm reduction as:

> Policies and programs which attempt primarily to reduce the adverse health, social and economic consequences of mood altering substances to individual drug users, their families and their communities (International Harm Reduction Association n.d.).

Lenton and Single (1998) critiqued some of the definitions of harm reduction and offered their own definition:

> A policy, program or intervention is one of harm reduction if and only if (a) the primary goal is the reduction of drug-related harm rather than drug use *per se*; (b) where abstinence oriented strategies are included, strategies are also included to reduce the harm for those who continue to use; and (c) strategies are included which aim to demonstrate that, on the balance of probabilities, it is likely to result in the net reduction of drug-related harm (Lenton & Single 1998. p.216).

In this regard, harm reduction consists of those actions that have reducing harm as the principle objective; thus strategies are directed primarily at the reduction of harm rather than primarily at the reduction of drug consumption. Reducing use or abstinence can be appropriate strategies within harm reduction policies, as long as the policies meet the criterion of focusing on the reduction of harm as the primary goal.

355 For further discussion as to how harm reduction is conceptualised and defined, see Drugs and Crime Prevention Committee 2002, 2004 and 2006.

Chapters 4 and 7 provide an example of harm reduction in relation to temazepam capsules. They have outlined how the combined strategies of providing information about the risks of injecting temazepam, the reduced access to these drugs through limiting their availability on the Pharmaceutical Benefits Scheme (PBS), and finally, with the co-operation of the pharmaceutical industry, removing them from the market effected a reduction in harm. Importantly, a key feature of the initiative was the focus on implementation across several organisations, engaging the support of professionals, those responsible for the regulatory system and consumer groups. Effective harm reduction strategies will frequently ensure that there is good engagement with consumers. For example, in relation to one specific strategy, Mr John Ryan from Anex observed:

> The reduction in temazepam gel caps is a great success, both with supply control at the prescribing end, combined with a collaborative approach with pharmacists and with health services dealing with drug users on a day-to day-basis, and with the Victorian Drug User Organisation. It was a very good example of a linked up approach, combining all of the elements of the harm minimisation framework, based on the understanding from experience that a supply control methodology only is unlikely to be successful.[356]

Drug reformulation can also be seen as a harm reduction measure. For example, in Chapter 7 there was a brief discussion about how drug re-formulations could reduce the potential for diversion and misuse (although sometimes unintended increases in harms can also arise from such formulations). For example, Suboxone® is a new formulation of buprenorphine that includes naloxone. If a person who is opioid dependent injects this new formulation, they will experience withdrawal symptoms. If taken as intended (sublingually), the medication will have the intended effect, thus ostensibly reducing the diversion and abuse potential. However, it is important to acknowledge that the introduction of this new formulation in Australia is too recent to have been fully evaluated.

Harm reduction: Issues requiring further consideration

While the principles and practices of harm reduction can be readily applied to pharmaceutical misuse, some particular harms that can arise from such misuse require emphasis. Anex identified a number of these issues, particularly in relation to the injection of pharmaceutical drugs that have not been developed for that purpose, which could result in injection site damage and vascular disease.[357]

356 Mr John Ryan, Chief Executive Officer, Anex, Association for Prevention and Harm Reduction Programs Australia, 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 Hearing, Melbourne, 20 June 2006.

357 See also Chapter 4 of this Interim Report.

> Whilst there are a number of harms associated with injecting any substance including scarring around repeat injection sites, infection from non-sterile injecting practices and the risk of 'dirty hits' among others, the variety and severity of injection-related health problems increases markedly when benzodiazepines and other pills intended for oral use are administered intravenously.
>
> Such harms include scarring and bruising of veins, difficulty finding veins to inject into, infection, abscesses, 'dirty hits', damage to the heart, lungs and capillaries, swelling of hands, arms, legs, blood clots and thrombosis, gangrene and in severe cases – amputation (Breen et al 2004; Dobbin et al 2003). Prior to the withdrawal of temazepam in 2002, a significant number of those injecting the liquid contents of temazepam gel caps were suffering acute health consequences including serious vascular damage, blood clots, thrombosis and gangrene (Dobbin et al 2003). The harms associated with misuse of temazepam were unprecedented and resulted in the eventual removal of temazepam.
>
> Injection-related health problems can be associated with the chosen injection-site. For example, there are specific harms associated with injecting into the femoral vein (or groin injection). Anecdotal evidence suggests that this may be a preferred site for particular cultural groups to avoid detection of their drug use.
>
> Both opioid and stimulant pharmaceutical tablets that are injected carry the risk of injecting travelling particles (when not filtered adequately prior to injection). The injection of tablets containing talc has been linked to chronic inflammatory granulomas in the lung. This can lead to respiratory failure and potentially lethal pulmonary hypertension.[358]

With regard to vascular and other health problems in particular, Mr Ryan outlined how such damage could be prevented through the provision of a better and wider range of harm reduction equipment:

> There is a limited range [of equipment] and I am sure that, as the role of the Needle and Syringe Program and our understanding of injecting drug use has expanded, the actual range of equipment has not expanded to keep pace with our understanding. For example, there are people using unsterile water for injection because needle and syringe programs do not distribute water free of charge. There are people sharing spoons and other mixing devices because needle and syringe programs are not able to distribute that equipment. There are no filters available, even cotton wool filters, but certainly in relation to the pill injecting there is no pill filter distribution throughout the Victorian Needle and Syringe Program.
>
> That might seem like a minor issue if you only think about injecting drug use as the risk of HIV, but as other people have mentioned today and as I have touched upon here, the risk of injecting benzodiazepines goes to gangrene and

358 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

> goes to other injection related harms. The only way that we are dealing with that at the moment is a very patchy access by some needle and syringe programs to pill filters based on a cost recovery basis. This is a good stopgap measure but it does not address the issue of injecting drug users' financial capacity to minimise their risk of injection related harms. Whilst we are certainly concerned about those individual risks, it is reasonable to think the community would also be concerned about the health consequences and costs of that damage. In which case it is quite clear that the cost of providing a diverse range of injecting equipment that addresses the realities of injecting drug use would be a saving for the health dollar in terms of the prevention of damage leading to, for example, hospitalisation.[359]

Anex stressed to the Committee how essential it was to provide a range of equipment that could help prevent the harms that can arise in relation to (inappropriately) injecting pharmaceutical drugs. Of particular importance, in Anex's view, is the provision of what are known as 'wheel filters':

> Filtering of tablets and pills is vital in reducing the harms associated with injecting substances that are intended for oral administration. Wheel filters (sometimes called pill filters), are the best way to filter any solution. Filtering pills and tablets is a practical way to reduce the number of particles being injected and the associated vascular damage.
>
> Wheel filters contain gauze which is capable of removing very fine particles and are designed to filter specific particles like chalk or wax. Current injectors will sometimes filter substances using cotton wool (which is useful) but this method will only filter down to about 50 microns. If cotton wool is the only filtering method, particles can still enter the bloodstream once the drug is injected. To ensure the risks associated with injecting pills are minimised, filters come in a variety of sizes (useful for filtering various particles and substances):
>
> - 5.0 micron – the biggest filter designed to remove chalk and binding agents from prescription medications like benzodiazepines and pharmaceuticals (also filter drugs like dexamphetamine and ecstasy). Filtering is most effective if a smaller filter is used following this
> - 0.8 micron – this is suitable for most substances (including MS Contin and OxyContin)
> - 0.2 micron – these filters are particularly useful for removing bacteria.[360]

Anex emphasised that the risks associated with pharmaceutical misuse, particularly the risks associated with injecting, provided a strong case to invest in such equipment. However, it was also stated that there were some current

359 Mr John Ryan, Chief Executive Officer, Anex, Association for Prevention and Harm Reduction Programs Australia, 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 Hearing, Melbourne, 20 June 2006.

360 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

cost-disincentives for clients, and there was a need to develop client skills to ensure effective use of the equipment:

> Anex believes the provision of wheel filters to injecting drug users is an essential harm reduction strategy. While it appears that users are requesting more information and access to wheel filters, many NSPs do not provide them due to cost. At present, some primary NSPs offer wheel filters to clients at a cost of between approximately $1.30 and $1.50 each. However, the cost associated with purchasing filters is a serious barrier to access and use.
>
> While wheel filters are an important harm reduction mechanism, they are not without their limitations. The complexity and extra time involved in using a filter requires some patience in the initial stages. If too much solution is pushed through the filter too quickly, they can leak. However, once the skill is mastered, they are easy to use and very effective in filtering particles that could otherwise cause serious vascular damage.
>
> Despite the difficulties identified, the provision of such equipment would be a practical strategy to reduce some of the harms associated with injecting benzodiazepines and other pharmaceutical drugs.[361]

The Western Region Health Service's submission to the Inquiry also proposed that enhanced access to such equipment should be provided to reduce the well-documented harms of injecting pharmaceutical drugs not intended for injection.[362]

Finally, another example of what could be called a harm reduction is the practice of dispensing or administering benzodiazepines and/or other prescription drugs in limited quantities. Such an initiative has been suggested to the Committee from a number of sources including the Turning Point Alcohol and Drug Centre:

> An appropriate modality for dispensing benzodiazepines to drug dependent clients is through daily dispensing, which is occurring in increasing numbers. This practice, however, raises a number of concerns related to costs of providing the service. Currently there is no PBS or other government funding source to provide for dispensing costs.
>
> The PBS payment for the prescription is generally for a month's supply, therefore, for pharmacies to dispense in this way they will only receive one dispensing payment for dispensing 30 times on the prescription. Given the social and economic disadvantage of many opiate dependant clients, they are usually unable or unwilling to pay for this service. In addition, PBS regulations preclude surcharging. Many pharmacists dispensing alcohol and drug dependence treatment have advocated for daily dispensing charges to be a

361 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

362 Submission of Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

> PBS-funded service – a model that is also advocated by many with regards to methadone (Muhleisen, 2002*)*.[363]

Harm reduction – enhancing quality of life

Harm reduction can also address quality of life issues, such as accommodation, primary health care and safety. The submission from Anex indicated that some work is progressing in this area, although no evidence was provided about the reach or effectiveness of these services specifically for those who misuse pharmaceutical drugs:

> Five primary health services with co-located NSPs have been established as a result of the initial strategy and offer a variety of health services to people who inject drugs. Services such as Living Room in central Melbourne operate from a social model of health to 'promote optimal health and well-being to diverse and marginalised communities in the central business district of Melbourne by incorporating the principles of harm reduction and primary health' (Living Room 2003).[364]

Anex described some broader roles of needle and syringe programmes in harm reduction. These programmes can potentially deliver opportunistic and brief interventions[365] to a proportion of the people who are likely to be at high risk of harm:

> NSPs are in a unique position to provide a range of harm reduction interventions with people who inject drugs, including a range of brief interventions. Many of these interventions will be opportunistic and are framed by a harm reduction approach. These can include, but are not restricted to:
>
> - Low-level opportunistic interventions such as posters and information displays; the provision of pamphlets with injecting equipment;
> - At the next level a client may have a quick chat with a service provider about safer injecting practices; may be provided with some verbal information on vein care or overdose risk;
> - At a higher level (and dependent on staff and service capacity), there may be time set aside for an activity or group discussion/information session or a confidential space to discuss issues and provide opportunities for referral to other health services.
>
> The importance of NSPs as a first point of contact and as a referral point should not be understated.[366]

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363 Submission of Turning Point Alcohol and Drug Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, May 2006.

364 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

365 For a discussion of the cocept of 'brief interventions' in the context of addressing drug abuse, see DCPC 2006.

366 Submission of Anex to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

In summary, the nature of pharmaceutical misuse, and the associated risks and problems, are legitimate targets for harm reduction strategies. As well as general risks that are often underestimated, there are specific risks associated with modes of use, especially injecting drugs not intended for this purpose. These risks differ somewhat from injection of heroin, requiring some refinement of harm reduction interventions and access to different equipment and processes to reduce risk. As mentioned in Chapters 2 and 4, combining pharmaceutical drugs such as benzodiazepines and narcotic analgesics with other central nervous system depressants significantly increases the risk of overdose. Harm reduction information, education and responses should be directed to reduce this risk. These strategies may require a review of the expertise of those who deliver harm reduction services, a review of the adequacy of current resourcing and the development of some specific information and education resources.

Finally, there are some interventions that in a broader sense could be considered harm reduction strategies. These might include examination of the scheduling or rescheduling of specific drugs, in order to make it more difficult to access a drug without a prescription, permit or authority. They may also entail a review of the potential value of the re-formulation of a drug in order to specifically reduce the harm associated with it (while at the same time formally assessing any unintended increase in risk that can arise from re-formulations). These potentially valuable strategies have been discussed in more detail in Chapters 6 and 7 respectively.

Conclusion

This brief review of the role of information, education, training and harm reduction in strategies to prevent and respond to pharmaceutical misuse has identified some important areas for further investigation. There appears to be a need to review and enhance coordination of the provision of information and education to the broad community and to particular target groups such as people who misuse pharmaceutical drugs. Although there are a number of services providing such information, there are also important gaps in information and a lack of a systematic approach in delivery.

Education and training and complementary strategies can ensure more health care staff effectively prevent, identify and manage pharmaceutical misuse. There is a need to review current provision and uptake of programmes. As is the case with information and education provision, it appears there is a need to consider a more systematic and coordinated approach to training. Compared to health care staff, the education and training needs of key groups such as police and local government staff appear to have been neglected.

Harm reduction strategies also have an important role to play in reducing particular risks and harms associated with pharmaceutical misuse.

Questions identified in this chapter that need to be considered in the ongoing inquiry are listed below.

Questions for further consideration

What are the information needs of

- The broad community
- People who are at risk of pharmaceutical misuse
- People who are misusing and/or are dependent on pharmaceutical drugs?

Is there a need for a more systematic approach to information and education and is there a need for central coordination for such initiatives?

What are the best approaches to develop and deliver information and education related to pharmaceutical misuse?

Could labelling and consumer medicine information (CMIs) be improved in both content and format? Has any research been done to see how effective such mechanisms are?

What harm reduction strategies are most appropriate and what are the implications of these strategies for resource provision and skill development?

What are the education and training needs of the health, police and other professional groups who respond to pharmaceutical misuse?

How should such education and training be systematically developed, implemented and coordinated?

9. Treatment Responses to Benzodiazepines and Other Forms of Pharmaceutical Drug Misuse

Introduction

Responses to the misuse and abuse of pharmaceutical medicines should ideally involve strategies to ensure legal and regulatory compliance, law enforcement approaches to prevent forgery and diversion, and information, education, and harm reduction strategies to prevent and reduce harm. Treatment has a complementary and important role in responding to pharmaceutical misuse and dependence.

Effective treatments for drug-related problems reduce mortality and improve the health, wellbeing and overall quality of life for individual drug users and their families. Effective treatment results in benefits for the broader community, not just those who use and abuse drugs. For example, methadone maintenance treatment has reduced the risk of blood borne virus transmission and reduced involvement in criminal activity, especially acquisitive crime. It is important to recognise that no single treatment approach will suit everyone in all circumstances. There are a wide variety of drug problems, of varying degrees of severity, occurring in diverse individual contexts. This indicates the need for a range of interventions, matched to individual need and circumstances and individual preferences. What may be effective for one individual in one context may not be helpful or necessary for another.

This chapter will examine the treatment of drug problems in general and the constraints on and barriers to effective treatment service delivery. It will then focus on the various treatment strategies that can be used with people who misuse and/or are dependent on pharmaceutical drugs.

Principles of drug treatment

The following principles for treatment have been described by Allsop (2000) and are based on the Principles of Effective Treatment developed by the National Institute on Drug Abuse (2000).

Treatment is cost-effective: Investment in treatment has consistently been demonstrated to make substantial savings in a variety of domains, including health, policing and the criminal justice systems. Treatment reduces the financial burden of drug use for the whole community.

No single treatment will be effective for all individuals: Like all health problems, no single intervention will be effective with all individuals. For example, for some people who are dependent on heroin, methadone maintenance treatment is a very effective intervention, associated with substantial improvements in health and wellbeing and reductions in criminal involvement. However, for other people, methadone maintenance treatment is not attractive or effective and they may be more suited to abstinence-based interventions. What might be a useful intervention for a homeless young man who is alcohol and benzodiazepine dependent may not be suitable for a retired woman, with a supportive family, who as a consequence of poor prescribing practices has become dependent on narcotic analgesics. It is important to have a range of modalities with demonstrable effectiveness to facilitate informed client choice of the most effective intervention. Treatment needs to be matched to individual characteristics, their unique experience of drug-related harm and informed choice of the most appropriate treatment goal and treatment method. Facilitating informed choice can demand high level clinical skills.

Treatment needs to be available and accessible: The more barriers there are to entering treatment, the less likely an individual will be to enter, adhere to, and be retained in treatment. Many services for people with drug problems are relatively inaccessible (geographically, times of operation and/or financially) and often have waiting lists. This problem is exacerbated for some sections of the community, such as Indigenous people, people living in remote areas, young people or parents with young children. An individual's motivation to change is influenced by circumstances at the time. If services are not accessible at a time when the individual wants help, a valuable opportunity to reduce harm may be lost. Consistently, evidence indicates that treatment effectiveness is affected by treatment retention. Inaccessible (and unattractive) interventions have poor retention rates and associated poor outcomes. They also reduce the potential to exercise meaningful treatment choices.

Treatment needs to attend to the multiple needs of the individual: Drug use and related harm do not exist in a vacuum. A large proportion of people who experience drug problems will experience problems in family, physical and mental health, legal, financial and other lifestyle domains. For some, the

drug use will be inextricably linked to problems that existed prior to drug use (for example, sexual abuse; mental health problems) and to current quality of life issues. Effective interventions are often those that enhance, or are associated with improvements in, quality of life subsequent to any change in drug taking behaviour. Thus, relapse risk is higher if a person gives up harmful drug use and his or her quality of life is still poor.

Combined interventions are often the most effective: Interventions that attend to the variety of client needs are often more effective treatments. For example, combining pharmacotherapy with psychosocial counselling strategies and lifestyle supports is often more effective than any single strategy on its own.

Treatment needs should be continually monitored and adapted to changing needs: At different stages of an intervention, an individual may have different treatment requirements. For example, in the initial stages residential or community-based withdrawal strategies may be indicated. Sometimes withdrawal management is enhanced by pharmacological interventions. Subsequently, an individual may benefit from specific interventions or medication to reduce the risk of relapse; interventions to facilitate improved family life; social services and legal advice to assist with problems accumulated during drug use; and sometimes psychotherapy for enduring psychological problems. When the selected intervention(s) proves ineffective, alternatives may need to be examined and introduced.

Treatment is appropriately matched to stage of change: Different individuals are at various stages of the change process. Some will be relatively content with their drug use and have little or no intention to change. Others may be in conflict about their drug use, but have no firm commitment to change. Some may have made a recent decision to make substantial change while others will have maintained a major change in drug use over many months or years. Clearly interventions will need to be matched to the various stages. For example, for the first group, interventions that provide information about risk and how to reduce risk (for the drug user and others) may be useful. For the next group it may be useful to engage in strategies to facilitate informed decision making about drug use and to follow this with practical strategies and skills that facilitate a decision to change. Finally, maintenance of change is often associated with increased access to and realisation of improved quality of life.

Co-existing mental health and drug-related problems should be treated in an integrated way: There is a high prevalence of co-existing mental health and drug-related problems. That is, many people with drug-related harm also experience mental health problems and vice versa, and treatment systems for

people with such problems often fail them. The treatment systems should be designed to respond to the co-occurring needs of clients who present for either condition. That is, to respond to the mental health problems of clients who primarily present for drug-related problems and vice versa.[367]

Coercion into treatment may help engage in treatment but is not sufficient to ensure good outcomes: There is increasing reliance on coercion to help engage people with the treatment system. The evidence indicates that coercion into treatment may help engage some people in the treatment system (for example, see Wild 2006; Drugs and Crime Prevention Committee 2006), However coercion alone is insufficient to ensure therapeutic engagement, adherence and good treatment outcomes. The quality of the subsequent therapeutic alliance between client and clinician is a critical ingredient of good treatment outcomes. If reliance is placed on coercion alone, the resulting reaction may work against treatment goals. That is, coercion is not a treatment – it is a way of helping some people get treatment but the outcome depends on the quality of the interventions offered and the quality of the staff providing those interventions.

Relapse is a frequent occurrence in the change process: Most people who successfully change will experience several lapses or relapses during the process. This is not unique to dependent drug users – many people find it difficult to change frequently practised behaviours. Treatment strategies need to include recognition of relapse risk and integrate responses to prevent and manage relapse.

Treatment outcome should be determined along several dimensions: Treatment outcome should not be simplistically determined, for example as failed/successful or using/abstinent. Just as there are many problems that may arise from drug use, so should there be many levels of intervention and

367 The issue of 'cross over' between drug dependence and psychiatric illness is an extremely vexed issue that has major implications for effective treatment modalities. In general terms this issue is discussed at length in a number of Drugs and Crime Prevention Committee reports (see in particular Drugs and Crime Prevention Committee 2004, 2006).

In the context of this Inquiry local clinicians have commented upon the failure of both diagnostic and treatment services to adequately address co-morbidity issues. For example, Dr Matthew Frei of the Interhospital Liaison Group stated to the Committee at a Public Hearing:

'I think we are recognising that a lot of people are using prescription drugs prescribed inappropriately and in large amounts to treat their own mental illness because they have not had it diagnosed or reined in properly. It is difficult, when people are using drugs in an uncontrolled way and withdrawing a lot when they cannot get them and getting back on them and taking too many, to try to decide if they have a mental illness. It is very hard because they might be in withdrawal and when people are in withdrawal they get agitated and sometimes they can get psychotic. Certainly the so-called personality disorders which are arguably a mental illness – the personality disorder type mental illness – seem to be quite common in a lot of this group; people with very difficult personality types, challenging personality types. But it is very hard with the so-called high-prevalence disorders like anxiety and depression to tease them out from the effects of the drugs. The drugs might be causing depression or withdrawal might be causing anxiety, so it is really difficult. It really clouds the diagnosis for people with two morbidities – with mental illness and drug dependence' (Dr Matthew Frei, Addiction Medicine Physician, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006).

treatment outcome. For example, treatments might be assessed on the basis of their capacity to reduce drug use, to reduce criminal involvement and/or to enhance health and quality of life. Thus, even though a person may continue to use drugs, changes in patterns of use, significant reductions in criminal involvement and enhanced physical and mental health will be indicators of positive impact. Alternatively, abstinence alone is not a sufficient indicator of successful treatment if other aspects of the individual's life have not improved – miserable abstinence is not an ideal treatment outcome.

Treatment might need to respond to the needs of 'significant others': Family members (or others who are part of a client's life) can be a barrier and/or a facilitator of change and good treatment outcome. A number of effective treatments have included a component that engages the family member(s) in the intervention. In addition, family members may be adversely affected by drug use and by any attempts to change drug use. That is, family members often have their own needs. Treatment/support resources need to be available to support 'significant others' and to provide advice about the process of change and treatment for drug users.

What kinds of interventions are appropriate for benzodiazepine and other pharmaceutical misuse?

There is little specific evidence about effective interventions for people who misuse and/or are dependent on pharmaceutical medicines. This is particularly the case for benzodiazepine misuse (for example, see National Center on Addiction and Substance Abuse at Columbia University (CASA 2005)). In the absence of quality evidence about the treatment of pharmaceutical misuse and dependence, treatment would generally be similar to procedures adopted for dependence on other drugs, such as alcohol and heroin dependence. However, given the lack of explicit evidence, some caution should be exercised, as there may be some specific characteristics of the individuals and/or the drugs that demand variations, or particular emphases, in treatment.

The need for a variety of treatment interventions

As described at the beginning of this chapter, effective responses are likely to involve a range of interventions, depending on the various needs of the individual. The following case study presented as Figure 9.1, provided to the Inquiry by the Interhospital Liaison Group, illustrates how one individual patient will have a variety of treatment needs:

A case study

A 59 year old lady presented to hospital for management of anaemia. She was living alone, at home, having separated from her husband and was estranged from her children. She was unemployed.

Over the previous 3 months, she had become increasingly short of breath, had reduced exercise tolerance and had multiple episodes of hyperventilation, anxiety and tremulousness. She was found to have a low haemoglobin but when she presented for further investigations, she was found to be too intoxicated with alcohol for a gastroscopy to be performed safely.

She had a past history of:

- Falls resulting in fractures to her left arm
- Suicide attempts by overdose
- Social isolation.

She had developed a significant alcohol dependence which she described as a response to receiving inadequate benzodiazepine dosage. A history of chronic benzodiazepine dependence emerged. She had first been prescribed barbiturates when 14 years of age, in response to symptoms of agoraphobia. Subsequently, she had used benzodiazepines continually, escalating in doses up to 24mg of alprazolam per day (equivalent to 240mg diazepam per day).

When her doses were reduced, she described increasing social dysfunction and limitation of daily activities due to anxiety. She had developed a significant pattern of helpless and hopeless psychological themes and fitted into the diagnostic criteria for borderline personality disorder. There had been multiple instances where clinicians had refused to prescribe her high doses and she had experienced prolonged withdrawals. She described frequenting up to 7 General Practitioners concurrently to gain a supply of benzodiazepines. Her dissatisfaction with treatment and ongoing poor response to medications resulted in her drinking heavily for 4 years. She attended a residential detoxification unit for alcohol dependence but started drinking soon after leaving there.

Her treatment is ongoing but difficult. She was given 3 units of blood and the cause of her anaemia continues to be investigated, with gastroscopy being normal and colonoscopy yet to be performed. There has been a focus on developing an integrated care plan that addresses drug dependence and psycho-social issues concurrently. Limits have been set upon her access to benzodiazepines and dosing is within strict limits (currently 35mg diazepam daily). The first step in reducing benzodiazepine dependence was to change short acting medications like alprazolam to diazepam, so that the actions of the medication do not fluctuate over the day. There is a need to address coping strategies for insomnia and anxiety accompanying benzodiazepine and alcohol withdrawal. Most difficult is the adjustment to a different world view, one which is not continually cushioned by the sedative effects of alcohol or high dose alprazolam.

> Outpatient management is complicated by the issue of how best to supply benzodiazepines in a long-term reduction dosing regimen. In her case, supply is by twice-weekly dispensing. However, it is difficult to manage the issue of her returning to accessing medications from multiple prescribers. The current regulatory framework and lack of real-time monitoring of prescriptions contribute to this problem.
>
> …Patients often misreport their consumption of these drugs, and given the variety of sources of benzodiazepines in the community, it can be difficult to assess extent of useage. Benzodiazepine use in conjunction with other substances such as alcohol can make the management of withdrawal difficult. These drugs carry a risk of overdose, particularly when combined with other sedatives. Management of benzodiazepine dependence usually requires long term and close follow up (often over months) as patients gradually withdraw.[368]

As this case example illustrates, treatment involves a range of strategies, including case identification and diagnosis, assessment and treatment planning, possibly withdrawal management and counselling, and management of other health problems that are caused by, or are coincidental to, the pharmaceutical drug problems. Sometimes treatments may be provided on an inpatient basis and other times as an outpatient. Some people will benefit from long-term residential service while others may not. It is not feasible here to thoroughly examine the evidence about all treatment options. What follows is a brief description of the range of options, some of which will be necessary for all patients and others will be tailored to suit particular needs. Some of the barriers to treatment will also be discussed. The following description is based on information provided in various treatment literature and clinical guidelines (for example, Hulse, White, & Cape 2002; Jarvis et al. 2005; Shand et al. 2003; Ward, Mattick & Hall 1998).

Identification/screening/diagnosis

It seems obvious that in order to be provided with effective treatment a person has to be identified as being in need. While this may at first instance appear axiomatic, for pharmaceutical medicines such as benzodiazepines and narcotic analgesics this may not always be evident. Patients, and members of the community, do not always consider pharmaceutical use and misuse as potentially leading to drug-related problems and dependence:

> One of the issues that we see, particularly in the hospitals and it is reflected in the treatment services, is that it is across all socioeconomic strata. It is not just typical drug users. In fact, they are probably easier to treat. It is the middle-class, middle-age women who come in with benzo abuse and trying to help

368 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.

> them see that they have a problem – they usually hang on to, 'But my doctor gave them to me' – that they are in fact addicted, and how you treat them becomes problematic because they are from a different mindset.[369]

Even if such patients do understand that they have a problem, they might not consider that they have a 'drug problem' and will resist any such identification, diagnosis or treatment programme. Others will actively disguise their drug use as a means to secure a further supply and, as indicated by a number of submissions to the Inquiry, some become quite skilled in this role.[370] Sometimes a medical practitioner will not see a patient frequently enough to be able to identify a problem:

> One of the things to remember is that a particular practitioner may not see the problem, because it may not be captured temporally – they might see a patient for a week and then not see them again – or the patient may be going to multiple doctors and multiple pharmacies. So it can sometimes be very hard to even know that there is an issue. That is where we struggle sometimes when we have managed to reduce someone's dose in an inpatient setting or through ongoing management over a period of months and we do not really know how things are going because there is no way of centrally accessing information that is timely.[371]

Conversely, some medical practitioners do not have the requisite skills or inclination to apply these skills:

> [W]e know from research in the drug and alcohol field, not only in this country but elsewhere in the world, that there is a widespread problem with medical practitioners under-recognising or under-diagnosing the condition of drug dependency. It is basically not well known or understood what the reasoning behind that is. Several theories are advanced but no-one fundamentally knows.
>
> Some people say it may be prejudice; maybe they have not had enough education in the medical course or curriculum. On the other hand, it [the medical school curriculum] is too big and there are too many areas of advancement in medicine to be fitted into the medical course. So doctors are not ideally trained in everything. Sometimes the patients with these conditions are just overwhelmingly difficult for many doctors, and therefore it is simpler just to prescribe or move them on and not formally address the problem. There

369 Ms Ros Burnett, Clinical Nurse Consultant, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

370 See for example the submission of Dr Rodger Brough to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and other Forms of Pharmaceutical Drugs in Victoria, July 2006 and submission of the Australian Medical Association to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

371 Dr Frank Giorlando, Addiction Medicine Registrar, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

> are all sorts of reasons. But it is a well known and commonplace coalface experience that many doctors do not appear to recognise the problem until too late.[372]

These submissions clearly indicate that there is a need for the implementation of more effective education and training. The comments above from Dr McDonough are consistent with research into barriers to effective management of alcohol problems (Shaw et al. 1978) which indicated that not 'raising the issue' may well be related to several factors such as:

- **Role competence:** 'I have the skills to identify/diagnose the risks and raise the issue';
- **Role confidence**: 'I can raise the issue'. This might be related to confidence in one's own skills, but it may relate to the degree of support that the medical practitioner has. For example, do they have the resources to manage and/or refer the patient if they identify a problem? Is it too difficult to raise the issue if one then cannot readily refer the patient into an accessible and affordable treatment service?; and,
- **Role legitimacy**: 'It's part of my job to ask these questions'. While professional organisations have developed and delivered guidelines and training programmes that assert that it *is* a legitimate part of a medical practitioner's role to identify and respond to pharmaceutical misuse,[373] as Dr McDonough has suggested it is possible that not all medical practitioners accept this.

A further barrier may exist. As discussed in Chapter 7, while projects such as the Prescription Shopping Program do provide access to useful compliance *and* treatment information. In general, however, access to effective information and monitoring systems is currently inadequate, making the task more challenging – a point emphasised by the Interhospital Liaison Group.[374]

Client/patient engagement

The ability to effectively engage patients is critical during initial contact, and throughout any ensuing intervention. The Youth Substance Abuse Service (YSAS) described the importance of this skill. While the description was specific to young people, the principles are pertinent across all client groups.

> The first step in any of our treatments is that engagement process, which means that the outreach worker would spend some time with the young person getting to know them and getting from the young person what their objectives are

372 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 13 July 2006.

373 See Chapter 7.

374 Ms Ros Burnett, Dr Matthew Frei and Dr Frank Giorlando, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

> around a whole bunch of things, including drug use. It may be that they do not present to us with a problem with benzos, they might present with a problem with something else, and we discover in our discussion with them that of course they are also using these other substances. The worker would then, by a process of initial education, using the concept of harm minimisation, talk to them about the consequences of what they are doing and get some feedback from them about what they think they need to do about that.
>
> In the course of that relationship it may be that the young person says, 'Yes, well, actually this is causing me a problem. It's interfering in my life. My relationships aren't working. I can't get access to employment'. We are working at the pace that the young person is going at. At the same time we are trying to provide them with options and opportunities, which might then lead to a period of detox, and then considering where they live; what sorts of vocational education aspirations they have and try to create access to those opportunities; and provide personal support along the way. It is linking with what is available but trying as far as possible to provide close personal support. That might happen for a while and then of course we have the relapse where people start to get engaged in problematic drug use again, so we start again. But it is built closely around this relationship between the young person and the worker.
>
> [Drawing from] the psychotherapeutic literature, the concept of therapeutic alliance is … the centrepiece of our intervention. We are creating an alliance between a worker and the young person and, through the mechanism of that relationship, create positive interactions and interventions with other options. Some of those options are available within YSAS and some of them are available in other systems. But the worker's job is to make the links and to keep persevering over time, rather than see it as a brief episode.[375]

Effective engagement with a client is important and requires some degree of skill. This should be a feature of any professional education and training. However, successful engagement is unlikely if the clinician does not believe that identification and treatment of pharmaceutical misuse is a part of his or her role, or if (as Dr McDonough suggests) some clinicians are prejudiced against patients who misuse pharmaceutical drugs. Prejudice is inimical to delivering quality treatment and strategies should be developed to counter it.

Assessment and treatment planning

Coupled with screening and inseparable from diagnosis, assessment can help identify the nature of a drug problem, determine the need for intervention and help plan the nature and course of treatment. Effective assessment will identify amount of and patterns of use (how much, how often and for how long) and consequences of use. It may also involve:

375 Mr David Murray, Chief Executive Officer, Youth Substance Abuse Service, 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 Hearing, Melbourne, 20 June 2006.

- Identifying the drug using history

  What drugs are being used/misused? How much does the person use? For how long have they used? From where do they obtain the drugs?

- Assessing the consequences of drug use/misuse

  What problems are they experiencing? Are they dependent? Do they experience withdrawal symptoms? How severe are these symptoms?

- Assessing the existence of co-occurring problems

  These may predate, coincide with or be the consequences of drug use. They might include other physical health problems, legal problems, family and relationship difficulties and mental health problems.

- Identifying the functions of drug use

  For example, is the drug use related to dependence, drug substitution and/or is it related to coping with some trauma or other problems? Is it used to help with problems, which might re-emerge if use is stopped – for example, pain management, anxiety, sleeping disorder – and therefore require specific interventions for these problems?[376]

- Identifying high-risk situations

  Are there particular circumstances when the individual is more likely to use or find it particularly difficult to cope without the drugs?

- Identifying available internal and external resources

  An individual's resources (or lack of them) will determine the nature and intensity of intervention that is required. Thus, a homeless person will possibly require different interventions compared to someone who has an intact and supportive family.

The above list, drawn from key texts such as Jarvis et al. (2005), is not intended to be comprehensive but aims to provide some indication of the nature and functions of assessment. Assessment informs the nature of the intervention, for example the location (eg. does the person require residential treatment?), the intensity (eg. does the person require specialist intervention?), the nature (eg. does the person require medication to manage withdrawal?) and the goals of treatment.

Withdrawal management

If an individual has become dependent on benzodiazepines and/or narcotic analgesics, the first stage of treatment may involve withdrawal management. Withdrawal from benzodiazepines and narcotic analgesics can be uncomfortable and may involve some health risks, which require varying

376 For example see the submission from Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and other Forms of Pharmaceutical Drugs in Victoria, June 2006. In this submission Ms Cannard describes interventions that address some of these co-existing problems such as sleep disorders.

degrees of medical management. Withdrawal management can occur in a medical setting, or can be supervised in a home environment – the location is determined by considerations about which drug (or drugs) is the focus of the withdrawal, the severity of dependence, the presence of other health problems, the quality of the home environment and so on.

As noted in Chapter 4, withdrawal from some benzodiazepines can be protracted, requiring longer clinical management than might be needed for other drugs. Access to withdrawal management services varies:

> There are the withdrawal units which are funded for an episode of care by the DHS for seven days. Seven days for a detox or treatment of withdrawal is probably not enough in that setting. You either need to do it in a very intensive setting, like in a hospital not in a detox centre – they are different. Hospital has around the clock nursing, very intense – or you do it slowly in the community. The ways to manage it are usually hospital beds – we have some in the Western, but otherwise we do not have them – or counselling GPs about how to do it in the community, or outpatient services about how to do it in the community.[377]

There are some specific services for young people, such as YSAS, that supervise withdrawal. As David Murray, Director of the YSAS, stated to the Committee in this regard:

> We have three residential withdrawal units of our own. There are six within the state, and any needs that young people have for withdrawal should really be possible under the existing system. We have 16 beds at any one time and, while there sometimes is a bit of a wait for a period of residential withdrawal, generally speaking, if a young person is keen and committed to coming into a detox unit they get in. That particular issue should not be a problem. In addition to which, we have a number of home based withdrawal nurses. Where a young person has some type of support – either at home or in some type of environment where there is an adult providing some care – withdrawal can occur at home, because we will have a nurse visit that home. Once the doctor has done an assessment and there is a regime of withdrawal available, the nurse and the youth outreach worker will provide support to the young person in their home. I do not think that there is a case for a special arrangement around these medications. I think the system can encompass them as it stands.[378]

Management of benzodiazepine withdrawal requires some degree of skill and understanding of the withdrawal syndrome. Importantly, traditional drug withdrawal services may not always be specifically geared to meet the needs of

377 Dr Matthew Frei, Addiction Medicine Physician, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

378 Mr David Murray, Chief Executive Officer, Youth Substance Abuse Service, 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 Hearing, Melbourne, 20 June 2006.

those who are dependent on benzodiazepines – either because the patients are not attracted to drug specialist services, services with regard to benzodiazepines alone are very limited,[379] or because of the protracted nature of withdrawal as compared to the experience with other drugs.[380] People whose narcotic analgesic dependence is iatrogenic (caused by treatment) may be similarly disinclined to access drug specialist services for withdrawal management.

Counselling and support

After withdrawal management, a variety of counselling treatments may be required, depending on individual need. For example, counselling might be directed to underlying, or co-existing, disorders such as mental health problems or sleep disorders.[381] Counselling may be directed to engaging and retaining the client in treatment, developing informed decision making about drug use and developing coping skills to help make changes. Some patients might benefit from cognitive-behaviour therapy and/or attendance at community-based support groups (see, for example, CASA 2005). A submission from Darebin City Council also suggested that community-based support services could play an important role in Victoria:

> In one case, the group of women who met as a research discussion group decided to form their own support group, which continues to meet to this day. Support groups used to be a much more common and legitimised service component than is evident today. Medication therapies are possibly at the height of an individualised response to health and healing, yet for those facing benzodiazepine-related harms it is this individualised response that exacerbates many of the difficulties of everyday life. The antidote is social reconnection:
>
> "Group support so that women know they are not the only ones who are going through this, it would help to build their confidence and would hopefully lead to them getting off medication altogether" (Discussion group respondent).[382]

379 For example, as indicated in Chapter 3, some respondents to this Inquiry believe there is a sizeable group of people who do not abuse benzodiazepines in association with any other drugs – licit or illicit. Darebin City Council for example argues there is a:
'[g]ap for those who experience medication-related harms who are not illicit drug users, where no services exist' (Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and Other Pharmaceutical Drugs in Victoria, July 2006).

380 See for example Ms Ros Burnett, Dr Matthew Frei, and Dr Frank Giorlando, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

381 See for example Ms Ros Burnett, Dr Matthew Frei, and Dr Frank Giorlando, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

382 Submission from Darebin City Council, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

Pharmacotherapies

Pharmacotherapies (drug treatments) might be used to assist withdrawal or as a maintenance treatment (for example, as is the case with buprenorphine or methadone maintenance treatment) or to help reduce the risk of relapse (for example, naltrexone).

Unfortunately, there is a very poor evidence base regarding the most appropriate pharmacotherapies for benzodiazepine abuse and dependence (CASA 2005). Most evidence about pharmacotherapies for pharmaceutical misuse relate to opioid dependence. In the treatment of opioid dependence, the main options consist of:

- Buprenorphine:
- Methadone; and
- Naltrexone.

Each of these options will be discussed in turn.

Buprenorphine

Buprenorphine is used as an aid to withdrawal management and/or as a maintenance drug. There is a good evidence base regarding its effectiveness for both of these purposes. The Australian Drug Foundation (ADF) describes the advantages of buprenorphine maintenance treatment as follows:

> There are many benefits of being on buprenorphine maintenance, when compared with continuing the use of heroin:
>
> - Maintenance treatment holds the person stable while they readjust their lives. The person may decide later to work towards reducing their dose of buprenorphine until they no longer require medical treatment.
> - Using buprenorphine on its own is unlikely to result in an overdose.
> - Health problems are reduced or avoided, especially those related to injecting, such as HIV, hepatitis B and hepatitis C viruses, skin infections and vein problems.
> - Doses are required only once a day, sometimes even less often, because buprenorphine's effects are long lasting.
> - Buprenorphine is much cheaper than heroin.
> - Staying off heroin can provide the opportunity to experience more 'life opportunities', much greater personal happiness, more close and stable relationships with others, employment and more money to buy goods for personal enjoyment.
>
> As with any type of treatment or approach to heroin dependency, buprenorphine maintenance may be effective for some people but will not suit everyone. A doctor or drug counsellor who spends time assessing the person's

specific situation and explaining different options will recommend an approach that is appropriate for that individual.[383]

Methadone

Methadone can also be used in withdrawal management and maintenance treatment. However, for a variety of clinical reasons, buprenorphine is more likely to be used in withdrawal management. Methadone maintenance treatment is very effective for some patients and has been associated with reduced illicit drug use, reduced risk of blood borne virus, reduced criminal involvement and improved lifestyle. The types of programmes are described by the ADF as follows:

> Generally, there are two types of methadone programs:
>
> - a maintenance or long-term program, which may last for months or years, that aims to reduce the harms associated with drug use and improve quality of life; and
> - a withdrawal (short-term) detoxification program, which lasts approximately 5–14 days, that aims to ease the discomfort of coming off heroin.[384]

Methadone maintenance treatment is advantageous for some, but not all people who are opioid dependent will benefit – as indicated earlier in this chapter, not all treatments are suitable for all individuals. There are also risks associated with methadone (for example if it is poorly prescribed, if it is combined with other depressants or if it is diverted). Not all patients are willing to regularly attend a medical practitioner or pharmacist for daily dosing (see, for example, Ward, Mattick & Hall 1998). The ADF information on methadone cited in Chapter 2 is also pertinent in this context, so it is reproduced here:

> Many people believe that it is preferable for heroin users to stop taking drugs altogether. Although for some heroin users this is achievable, for others there is a high risk of relapse into heroin use. Methadone maintenance has helped many people reduce the recurrence of compulsive heroin use.
>
> Methadone treatment, like any other drug treatment, is not a 'cure' for heroin dependence. However, research has shown that it can improve the health of people dependent on heroin in a number of ways:
>
> - people are less likely to use heroin that may be contaminated with other substances;
> - methadone is taken orally, which makes it cleaner and safer than injecting heroin. This reduces the risks of sharing equipment and becoming infected with blood-borne viruses such as hepatitis B, hepatitis C (which may lead to long-term liver problems) and HIV – the virus causing AIDS;

383 The Australian Drug Foundation website. (Accessed at:: http://druginfo.adf.org.au/article.asp?ContentID=buprenorphine).

384 The Australian Drug Foundation website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=methadone).

- the routine involved in methadone treatment encourages people to lead a balanced and stable lifestyle – including improved diet and sleep;
- people are less stressed, as they do not have to worry about where their next 'hit' of heroin is coming from;
- methadone lasts longer in the body than heroin, so it only has to be taken once a day;
- it allows people to handle the withdrawal process with less discomfort;
- criminal activities conducted to obtain illegal drugs are reduced;
- it helps people cut their connections with the drug scene;
- it's cheaper – although there is usually a dispensing fee with methadone, this is relatively cheap compared to the cost of illicit drug use (the recommended dosage fee at the time of writing this information was $7.50, although this amount may vary between dispensers).[385]

Naltrexone

For those who are committed to abstinence, naltrexone may be a useful treatment option, as it used to maintain abstinence/reduce the risk of relapse (CASA 2005).[386] Naltrexone is an opioid antagonist, which means it blocks the effects of heroin and other opioids. This means that the euphoric and other effects of heroin, for example, will not be felt. The ADF advises that:

> …recent studies have suggested that many clients do not remain on naltrexone treatment and will often return to heroin use. More studies are currently being conducted that may provide a clearer picture of naltrexone's effectiveness. It is important to recognise that naltrexone treatment may be effective for some people, but will not suit everyone.
>
> To be eligible for naltrexone treatment, the following needs to be considered:
>
> - The person must be free of heroin and other opioids for 7–10 days, or 10 days for methadone, before commencing naltrexone maintenance treatment, otherwise there is a risk that the individual may experience acute, instant withdrawal.
> - Existing liver conditions, such as acute hepatitis, may exclude a person from naltrexone treatment.
> - If a woman is pregnant or breastfeeding further advice should be sought, as it has not been established that using naltrexone during pregnancy is completely safe.
> - People who are highly motivated to be opioid free and have support from family and/or friends are more likely to benefit from the treatment.[387]

385 The Australian Drug Foundation website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=methadone). Although as discussed in Chapter 4, whilst methadone is indeed designed to be taken orally, great harm can result from injecting it into the body.

386 See also Chapter 2 of this Interim Report.

387 The Australian Drug Foundation website (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=nalrexone).

It is important to emphasise that whilst these pharmacotherapies are likely to be useful for treating pharmaceutical narcotic opioid dependence, at least with some patients, the existing evidence-base is largely based on populations who are primarily heroin-dependent and caution should be exercised in generalising from these studies.

Relapse prevention

Drug dependence has been defined as a 'relapsing condition'. Effective interventions, in general, include pharmacotherapy (for example, the use of naltrexone) and counselling strategies to prevent and manage relapse and attention to lifestyle issues. YSAS states that in relation to young people they see who are dependent on benzodiazepines and narcotic analgesics a similar focus is required:

> Very often they do, [relapse] and we take the view that that is not necessarily evidence of failure. Many young people need to come through our system a number of times, particularly through residential withdrawal. For young people, having access to withdrawal is a place of safety, support and reconsideration. If they needed to use that service a number of times, we would support them in that, rather than say, 'You failed, don't come back'. We would use withdrawal, again, probably a little bit differently to the adult system. It would be about saying to young people, 'This is a place of safety and support for you to come back and reconsider what you're doing', and that might happen a number of times.[388]

Sometimes relapse can be viewed as an inevitable result of the gaps in, and inadequacies of, the treatment service system itself. For example the research conducted on prescription drug abuse in the municipalities of Moreland and Darebin found that:

> Few women [interviewed for the research study] had been linked to appropriate services as part of discharge planning. Several women agreed with the comment of one respondent that she had been 'in and out of hospital and never provided with a support service'. One woman who had overdosed on several occasions noted that 'The last time I came out of hospital after a medication overdose I was hooked up with a case manager and finally got the support I needed'.[389]

This was also certainly the view of individuals the Committee met with who had previously been dependent on prescription drugs:

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388 Mr David Murray, Chief Executive Officer, Youth Substance Abuse Service, 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 Hearing, Melbourne, 20 June 2006.

389 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

As a result of such a lack of follow-up, some women in the Darebin/Moreland area had formed their own discussion and social support group that continues to this day.

> [A lack of follow-up] is one of the huge problems. Right now, if you are in the public system, you get six nights to detox, no matter what the drug; alcohol, heroin, temazepam. I was in there for $6^1/_2$ months. It is crazy. You are in there for six nights, then you go home. Nine times out of 10 you are there on your own, at least during the day, if not 24 hours a day. You do not have your drug of choice any more. Most of the time you are alone which means you have the heebie-jeebies anyway. If you are lucky you have the one or two 24-hour helplines. I have rung those a couple of times. … These are the drug helplines and they are young. They are kids. They have not got a clue what you are talking about because they are there for the illicit drugs more than anything else. You think, 'You've got to be joking' and that is it.
>
> There is no point going onto a waiting list for counselling. How can you go onto a waiting list for counselling? If you need counselling, you need it now. But you cannot go onto a waiting list until you go into detox. You only have it for six nights. It does not make any sense.[390]

Another woman who gave evidence to the Committee commented:

> As soon as you come out of detox is probably when the suicide rates are at their highest, I would say. As 'Anne' said, you are on your own, going through hell. You cannot explain to anybody. When you have a very conservative background, in particular, you cannot ring up a family member to say what you are feeling. You cannot express what you are feeling. You just have to go into shutdown for that time.[391]

If such comments are indicative of a more widespread problem, it is certainly an issue that needs to be considered in future work of this Committee.

Assertive follow-up

One aspect of planning that is increasingly seen as an important part of any treatment regime and which may at least in part assist in relapse prevention is the concept of *assertive follow-up.* Assertive follow-up has been described as:

> [t]he practice of contacting clients of services who may have missed an appointment or not made a follow-up appointment. Assertive follow-up practices are also important to use with potential clients who have been placed on waiting lists and for people who have been assessed by a service and

390 'Anne', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

391 'Mary', Evidence given to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 20 June 2006. The name of the person who gave evidence has been changed to protect her anonymity.

> referred to a more appropriate service. These two client groups face a high risk of falling through service gaps.[392]

During the research into prescription drug abuse undertaken in the Melbourne municipalities of Moreland and Darebin, 'Assertive follow-up was overwhelmingly considered a key mechanism that led women towards further healing.' The authors continue:

> Assertive follow-up was often the trigger that encouraged women to seek additional support. It was a symbol that these women mattered and that someone was interested in their wellbeing. During information dissemination at the end of the research project, assertive follow-up was raised with a range of services – particularly family violence services – as a simple and effective strategy. The author wonders if this was remembered by any service as an intervention, if it was even heard in the first place. The overwhelming response from services when assertive follow-up was raised was that the services were already under significant pressure and that assertive follow-up was a luxury that encroached on worker time and resources. Yet emerging technologies are now available that would allow services to send a simple SMS to waitlist clients or as a reminder to those booked for their first appointment.[393]

Residential services

Some people, such as those who are homeless or whose home situation is not conducive to changing harmful drug use (for example, where others in the household are abusing drugs) or who are otherwise enmeshed in harmful drug use, may benefit from residential services. In evidence to the Committee, YSAS elaborated on the residential programme their organisation provides for young people:

> We have two small programs. One is called Reconnect, which is specifically designed for working with the young people and their families. Where they are at risk of homelessness because of their drug use, we would be working to try and keep the family intact. The second, which is becoming an increasing issue, is a parents program. We have young women, particularly, in our system who are children still, in a way, and they are having babies. So we have a one-person program focusing on the needs of parents, who tend to be young women, who have children already in our system. That is a difficult, sensitive question.
>
> We are very good at engaging young people. I think that, where there is some type of adult and/or family support and some type of secure and safe environment to live in, we are likely to be more successful than if they have absolutely no family support, no human adult contact or support, and are

392 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

393 Submission of Darebin City Council to the Drugs and Crime Prevention Committee, Inquiry into the Misuse and Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

> transient. That tends to be a prescription for it being more difficult to provide an intervention. In our residential rehab program which is more focused on young people who are ready for a defined, intensive four- to six-month treatment process, the key things are: somewhere to live that is safe; then engage in education and/or employment and training; and significant contact with either a family member or supporter or a worker that is providing ongoing mentoring and support. These are the features of more successful interventions. That is consistent with the evidence.[394]

However, access to these services, like all other services, is limited. Residential services in particular have substantial waiting lists:

> You are asking about waiting times. Long-term drug treatment, where people live in a supported residential setting or live on a farm or in a therapeutic community, the waiting times for those are very long. They can be several months, which tends to be fairly impractical.[395]

Alternative interventions

In addition to a focus on pharmacotherapies and counselling, it is pertinent to note that ongoing sleep disorders and anxiety might contribute to maintenance of pharmaceutical misuse and to relapse risk. Alternative or ancillary treatment services that address these problems are discussed further later in this chapter.

Managing patients who have obtained their drugs through doctor shopping

Managing patients who have obtained their drugs through doctor shopping require tailored interventions. For example, providing withdrawal management and counselling will have limited value if the person continues to obtain medication from another source. Dr Mike McDonough described the challenges of managing such patients and suggested some strategies:

> …I think a treatment plan is absolutely essential. Unfortunately, seeing some of the cases where things did go wrong, I cannot remember ever seeing a case where the doctors involved kept notes that indicated there was a treatment plan, and it is probably the most important and most commonly overlooked aspect of the care of these patients. These are, again, benzodiazepine-dependent patients who sometimes use multiple doctors or doctor shop and get into problems with the way they take these medications.

394 Mr David Murray, Chief Executive Officer, Youth Substance Abuse Service, 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 Hearing, Melbourne, 20 June 2006.

395 Dr Matthew Frei, Addiction Medicine Physician, Interhospital Liaison Group, 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 Hearing, Melbourne, 19 June 2006.

> The treatment plan should always involve one doctor and one pharmacist – that is, one dispensing point – and ideally one or other pharmacies working around the clock or working different days, getting to know the patient and picking up on some days where the patient does not look well. [In such cases] they may choose not to dispense until the patient has been sent down to the GP. Something like that is a regularly used technique in the management of patients on a methadone program, but it is probably not that familiar to many GPs. So it is just an additional form of monitoring – checks and balances.[396]

Dr McDonough also suggested there was a need for a permit system to obtain certain drugs, similar to that used for Schedule 8 drugs (see Chapters 6 and 7). He argued that such a system is an additional 'check and balance' in the system, whereby before a permit is granted a treatment plan must be evident. He spoke also of the need to ensure proper coordination of patient care occurred to reduce the likelihood of a patient receiving medications from more than one doctor.

> If we had a permit system whereby a patient was going to be treated with these tranquillisers – [such as] the benzodiazepiness – for an extended period of time, a permit, I believe, would be helpful. That would, as I have said previously, identify that this doctor is taking over the treatment, is attempting to be the one and only doctor. … If another doctor sees that patient unbeknownst to the primary treating doctor holding the permit, it is the professional responsibility of all other doctors to make sure that someone else is not prescribing, because if they prescribe when someone else has a permit, they are in breach of the regulation.[397]

In addition to proposing a permit system, Dr McDonough also discussed the merits of a peer review system:

> I think a better system would be to have a medical review panel where requests for permits or requests for continued prescribing long term of these potentially hazardous drugs is reviewed. Sometimes that may not be recommended and permits to treat may not be granted. Instead, the department may require that particular doctor to refer to a specialist agency for an intervention and reconsider the permit for that treatment later. … The regulation requires that the permit is requested before the other one expires, so even if the permit is about to expire, the department generally allows extension if there are reasonable circumstances, such as that there is a need to continue treatment because the peer review panel, let us say, does not meet for another month. Currently what happens if a permit runs out is that the doctor rings up and says,

396 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 13 July 2006.

397 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 13 July 2006.

> 'I have so-and-so in a lot of pain. I cannot stop their morphine. I will need the permit to continue because the patient cannot get in to see the pain clinic for another six weeks'. So then instead of the permit being issued for three, six or even twelve months, it is issued for six or seven weeks, pending the outcome of further advice from the pain management clinic.[398]

What treatment services are available to respond to pharmaceutical misuse?

There is a wide range of specialist drug services available in Victoria. Some of these are drug specialist services that respond to people who use prescription drugs in combination with other drugs (for example alcohol or illegal drugs). Some services may also see clients who are solely misusing pharmaceutical medications. Some individuals will not want to use drug specialist services. Instead they may prefer to use more generalist services, such as a GP, a community-based service or be treated in a hospital. This may be particularly the case, as was discussed in Chapter 5, if the person does not perceive themselves as having a 'drug problem'.

TRANX is an example of a service that specialises in responding to people who are dependent on the drugs considered by this Inquiry. TRANX provides education and training to professionals, and access to counselling and support. It also develops resources that help people cope with co-occurring problems, such as sleep-disorders:

> TRANX continues to provide a small counselling service and provides education & training activities to health practitioners working in alcohol & drug treatment, community health, and other related services to enable people with benzodiazepine dependency to access services close to home.
>
> Information and education is also provided to a wide range of health practitioners, including doctors, nurses and aged care practitioners to encourage safe use and prescribing of the benzodiazepines. Sessions focus on safe use principles and alternatives to benzodiazepine use for anxiety disorders and sleep problems.
>
> Sessions are also provided to members of the community on alternatives to benzodiazepines for anxiety and sleep problems. Community information sessions have focussed on women from culturally diverse backgrounds, seniors (including from culturally diverse backgrounds) and general sessions on anxiety and sleep management…
>
> TRANX has developed a number of resources:
>
> - Relaxation CD/tape
> - The Better Sleep Book

398 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 13 July 2006.

- "Benzos- what do you want to know?" – information sheet for young people
- "Pain relievers – what you should know" card
- Safe use of tranquillisers and sleeping pills information sheet in 17 community languages.

> The primary target group for TRANX counselling has been for people using low, prescribed doses of benzodiazepines…Existing service users of Health Works wanting to do something about their benzodiazepine use are linked in with the GP at Health Works. The GP, Community Health Nurses and the Community Health Workers then work with the service user to develop a treatment plan. Treatment plans are based on goals self determined by service users, as it is essential that they are making the decision about whether or not to reduce and when to reduce. In some cases the best outcome in the short term may be to stabilise the person and have them agree to only get their scripts from one doctor. Management of the dosage by one doctor lowers many of the risks associated with benzodiazepine use. Community Health Nurses and Community Health Workers are also able to provide the service user with extensive support around a range of issues in a way that a GP working in isolation wouldn't have the capacity to provide. A systematic long term approach is required in managing people with benzodiazepine dependencies. The demand for people needing support and management around their benzodiazepine use exceeds Health Works capacity.[399]

There is a range of other services, including the services provided by hospitals (eg. Interhospital Liaison Group; Western Region Health Centre) and individual GPs. However, it is difficult to answer the question as to whether treatment service provision is adequate, as there is little data or evidence that accurately indicates the number of people who are misusing pharmaceutical drugs and the number of these who successfully access treatment. This dearth of information is not unique to Australia. In a recent United States review it was stated that:

> No data exist that document how many of those who need treatment for prescription drug addiction receive it (CASA 2005, p.96).

Nevertheless, a cautious conclusion would be that not everyone who misuses pharmaceutical drugs accesses treatment. Explanations for this include the following:

- Not all people with any drug problem (alcohol; illegal drugs) access treatment for such problems;
- As indicated earlier, people who misuse and/or are dependent on pharmaceutical drugs may not recognise that they have a drug problem and may even actively resist such a diagnosis or categorisation;

399 Submission from Gwenda Cannard, Director, TRANX (Tranquilliser Recovery and New Existence) Inc., to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006.

- Services might not address the particular needs of individuals from some backgrounds (eg. culturally and linguistically diverse (CALD) or Indigenous people);
- Services may not be locally available; and
- A number of submissions to the Inquiry noted that there are waiting lists to access some treatment services.[400]

Anecdotal evidence to this Inquiry suggests that some groups appear to have more limited access to treatment than others. These groups might include people living in regional and rural areas, people with CALD backgrounds and parents with young children. In his submission to this Inquiry, Dr Rodger Brough commented on the difficulties in accessing services in rural and regional Victoria:

> …access to psychiatric support and psychiatric medical services is so restricted for many 'public patients' who do not meet the 'major mental illness' qualification that they are effectively denied access to services. This makes access to appropriate treatment options more difficult for people with a significant drug problem.[401]

However, even in metropolitan areas access can be a problem, as highlighted in the submission from Darebin City Council:

> While the state-based TRANX service offers ongoing counselling for those with benzodiazepine dependence, the service is located in Glen Iris and is beyond the access of many local residents. It is understood that waiting lists also fluctuate for this service, which may act as a barrier for those seeking immediate assistance. Forthcoming changes to the drug treatment service system also pose a possible threat to such services where counselling is the main therapeutic modality. Initial work on the drug service system review suggests a curtailing of counselling activities in favour of medication-based therapies which are simply inappropriate for this target group.[402]

Mr John Ryan from Anex expressed the view that for particular groups, such as CALD and Indigenous people, service provision was not ideal:

> It is difficult to generalize…There are some services that are working quite successfully but most services are not sophisticated in the way that they deal with cultural and linguistic diversity. Certainly, for example, we have been trying to find a mechanism to improve understanding amongst Vietnamese injecting

400 For example, see 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, and submission made by Western Region Health Centre to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

401 Submission of Dr Rodger Brough to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

402 Submission of Darebin City Council, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

> drug users of pharmacotherapies. They are the most effective opioid substitution treatments; the most evidence based. But there are significant barriers to their access which leave people stuck in the illicit drug market. One of the barriers is the generic way that services are provided. There is no specialist pharmacotherapy service for Vietnamese injecting drug users, let alone for Indigenous injecting drug users or any other group who are injecting drugs. It is a one size fits all approach and that does not fit.[403]

Darebin City Council also expressed similar concerns about identifying and meeting the needs of Indigenous people:

> Responding to the needs of Aboriginal and Torres Strait Islanders is a good example of how the disjointed funding impacts on inequitable health outcomes. The medications research project was funded for one year. Anecdotal evidence from a number of Aboriginal agencies indicated that medication misuse – in particular medication mismanagement – was impacting significantly on Indigenous residents due to the high level of medications many Indigenous people are prescribed. However, working in partnership with Aboriginal agencies takes time and the building of trust was not possible on a year long project that was broaching such personal subjects as overdose, sexual abuse, family violence, and polydrug use. One woman who identified as Aboriginal responded to an anonymous phone hotline held as part of the research…In the two years since this research was conducted, the researcher has been able to build stronger links with Aboriginal agencies and has developed working relationships to respond to health inequalities faced by Indigenous residents in Darebin, but this has taken three years. As a result, the opportunity was missed to uncover the impact of medications, including benzodiazepines on Indigenous residents of Darebin and Moreland, and this is still a significant gap in available research.[404]

Another problem identified during the Inquiry relates to barriers to service access. One such example is the limited times of opening for various treatment or ancillary services. Mr John Ryan from Anex commented in this regard:

> One of the other significant issues that this committee may consider in relation to benzo use is the hours of operation of NSP services. Most NSPs operate during business hours. Most drug consumption is a 24/7 around the clock, seven days a week activity. There are severe gaps not only in the hours of operation of needle and syringe programs in regional and rural areas, including issues of confidentiality, but also in terms of the Melbourne metropolitan area where come one o'clock in the morning people are not able to access any expertise in relation to their drug use issues. So there is no service at, say, 1am or 3am in the morning. There is a telephone service which is not nearly the same as actually

403 Mr John Ryan, Chief Executive Officer, Anex, Association for Prevention and Harm Reduction Programs Australia, 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 Hearing, Melbourne, 20 June 2006.

404 Submission of Darebin City Council, to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, July 2006.

> dealing with a health professional face to face and acknowledging that people will use drugs and they will use them by injection and, quite possibly, by risky injecting behaviours if there is not access to equipment.[405]

On a more positive note, there were some comments that suggested there have been improvements in service provision:

> We have seen in the last few years an increase in some services in the Melbourne metropolitan area called primary health care services. They have been very successful in terms of providing comprehensive holistic health access to people who are otherwise not accessing services, and that includes areas like Footscray and Dandenong, where there are high concentrations of vulnerable injecting drug users.[406]

It appears that there are indeed some barriers to treatment for people who misuse benzodiazepines and narcotic analgesics. However, the current information makes this difficult to quantify. This would be a pertinent issue to explore more fully in the future.

An illustration of the treatment process

It is useful to describe what might happen in the treatment process for someone who is misusing pharmaceutical medicines. In his presentation to the Committee, Dr Mike McDonough described how patients might be managed in his hospital services. His description is reproduced here in detail as it provides a practical illustration of the various steps of intervention. First, he described the initial contact with the patient:

> The patient would either come to us through the emergency department because there has been some drug-related medical problem, or they could be referred by a general practitioner or a drug and alcohol agency. It is rare in our service in the hospital to get people just walking in off the street; they are normally referred. Once they arrive they would be triaged. Some people would have predominantly psychosocial problems – for example, they have been thrown out of home, they are in trouble with the law, they have no money and are going into drug withdrawal and need detoxification or [a] time out type intervention. Many of those presentations would be dealt with by a trained counsellor, who is often a registered nurse or a social worker, who would try to prioritise the immediate needs and slot that person into the treatment program or day-to-day contact or outreach.

405 Mr John Ryan, Chief Executive Officer, Anex, Association for Prevention and Harm Reduction Programs Australia, 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 Hearing, Melbourne, 20 June 2006.

406 Mr John Ryan, Chief Executive Officer, Anex, Association for Prevention and Harm Reduction Programs Australia, 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 Hearing, Melbourne, 20 June 2006.

> However, if it is a medical problem, let us say the person has come in because they have had an overdose or a seizure related to the sudden withdrawal of drugs like benzodiazepines, I would firstly assess whether the person has an intermittent drug problem – sometimes called recreational drug abuse, or a dependency problem, meaning the person has acquired a daily habit that in turn requires that individual to have a supply that is regular and ongoing every day.[407]

As described earlier in the chapter, for many patients (that is, those who are dependent) the first step will consist of withdrawal management. This will help stabilise patients and enhance their capacity to benefit from other interventions, such as relapse prevention. There is also a need to identify and address any underlying problems such as mental health problems:

> Secondly, sometimes people's underlying psychiatric or other diagnoses can be revealed once you have removed the drugs – for example, many people look like they are very memory disturbed or behaviourally disturbed when they are continually drug dependent, but once the drugs have been removed they look quite different and perhaps they do not have memory damage or brain damage or a severe anxiety problem; [in other words it was part of] just daily withdrawal.[408]

While withdrawal management may be conducted in the hospital, the development of a rehabilitation plan is often conducted on an outpatient basis. However, for a small number of patients who have multiple problems, they may initially continue with inpatient care, or referral to a residential service:

> An example would be Odyssey House. Someone will have gone through a detoxification period and had a couple of weeks safe off drugs, monitored. They may not go back home; they may be kept in the detox unit or they may step down into a safe house or into the care of a family who are watching and making sure that they have not relapsed. Then they go directly to a place like Odyssey House, where they might spend months, or longer.[409]

The next stage involves relapse prevention, a particular concern for those who are opioid dependent. Dr McDonough suggests that for these patients who particularly have had multiple relapses, substitution therapy programmes are one way of avoiding relapses in the future:

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407 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 13 July 2006.

408 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 13 July 2006.

409 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 13 July 2006.

> …we know that the highest risk to their life is a drug overdose, and we know at the same time that the best medically proven preventer of overdose mortality for heroin addicts is pharmacological treatment, with things like substitute methadone or substitute buprenorphine.
>
> …the best advice [in such cases] would be going onto methadone. Some patients might in fact make that decision for you by telling you, 'There is no way I am going to Odyssey House', or, 'There is no way I am going to stop using drugs, Doc, but I'll try the methadone' – or the buprenorphine. In those sorts of cases we recommend they start this sort of pharmacological treatment. That is started usually before they leave the detox unit or sometimes as an outpatient. The program continues in the outpatient sector. They are twice weekly at first, weekly and then eventually every couple of weeks and, when they are running reasonably stable, monthly.[410]

As can be seen, treatment consists of several steps, requires a range of clinical skills and sometimes coordination across services. It is evident that such responses can be resource intensive. This last point is important. A number of agencies that have actively engaged in responding to pharmaceutical misuse indicated in their submissions that effective responses, accessible throughout the community, are beyond their current resources and beyond the means of many clients.[411]

A final comment on the needs of families of drug users

As indicated earlier, families have an important role in the prevention of drug related harm and they can have a major influence on treatment outcome. They also have needs in their own right. Despite this observation, the role of the family and its needs have historically been neglected. As the mother of a person once dependent on prescription drugs remarked in a letter to the Committee:

> I feel strongly about all aspects of drug use, the impact on the user and the fear and grief caused to families. If I can have our voices heard that is wonderful for all of us and it means our experiences haven't been in vain...though we wish we didn't have them.[412]

The neglect of families is also illustrated in a British study. In this study of illicit drug users (that is, not specifically pharmaceutical misuse), Velleman and colleagues (1993) found that the majority of participants (88%) in the study

410 Dr Mike McDonough, Medical Director, Drug and Alcohol Services, Western Hospital, 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 Hearing, Melbourne, 13 July 2006.

411 See for example the submissions from TRANX (16 June 2006), Anex (22 June 2006), Western Region Health Centre (5 July 2006) and Dr Rodger Brough (21 July 2006) to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria.

412 Correspondence from Ms Margaret Quon to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, 7 August 2006.

received some kind of support. This was categorised into informal support, such as that offered by friends, clergy or work colleagues (used by 74% of the sample), formal support, such as from a GP, psychologist or drug treatment service (60%) and self-help group support (34%). However, most of the study participants were dissatisfied with the support offered by formal services. A large proportion believed that they did not receive adequate help and/or they believed that the help that was offered was not useful.

In considering the treatment needs of people who misuse and are dependent on pharmaceutical drugs, it will also be important to consider the needs of families and significant others.[413]

Conclusion

Treatment for drug problems in general can be effective (eg. Loxley, Toumbourou & Stockwell 2004; National Institute on Drug Abuse (NIDA) 2000; Ward, Mattick & Hall 1998). However, the available evidence indicates that a range of interventions will be required for the diverse needs of an individual as they progress through the different stages of treatment (eg. Jarvis et al. 2005; NIDA 2000).

The Committee found that there are few modalities or services that are specific to treating or addressing pharmaceutical misuse and dependence. There is a particular limitation in relation to benzodiazepine misuse. In the absence of such evidence, the conservative approach is to adopt procedures and guidelines that are applied to other drug problems. Treating pharmaceutical misuse requires a particular focus on treatment planning, especially in relation to reducing the likelihood of continued prescription of medications by someone not involved in the treatment process.

There appears to be a number of barriers to accessing treatment, including the ability and willingness of some mainstream health staff to respond, limited access to specialised services such as TRANX, and much reduced access to services outside the central metropolitan regions. Some services have waiting lists, which can act as a barrier to effective engagement and treatment.

The prevalence of benzodiazepine and narcotic analgesic use and associated problems in some communities is not known and so it is difficult to assess the accessibility or adequacy of treatment services. This is particularly the case for Indigenous and CALD populations.

The analysis presented in this chapter with regard to the limitations of treatment modalities raises a number of issues. Treatment of drug problems in general is effective. Less is known about the treatment of benzodiazepine and narcotic

413 See for example the submissions from Mr Leon Hain (3 April 2006), Ms Margaret Quon (23 June 2006) and submission to the Drugs and Crime Prevention Committee, Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria, June 2006. The name of the author of the last mentioned submission has been withheld to protect her anonymity.

analgesic misuse. A range of individuals and services are providing treatment responses to people who misuse pharmaceutical drugs, but there is an urgent need to review treatment needs and the adequacy of treatment responses to benzodiazepine and other pharmaceutical drug misuse. There are many questions that require further consideration in the ongoing work of the Inquiry, including those in the following list.

Questions for further consideration

What needs to be done to build the evidence base and develop guidelines about the effective treatment of pharmaceutical misuse and dependence, especially in relation to benzodiazepines?

What needs to be done to build the evidence base for pharmacotherapies for benzodiazepine dependence?

What education and training is needed to assist mainstream health staff become more effective at preventing and treating pharmaceutical misuse?

What level and location of service provision is required to specifically and effectively respond to pharmaceutical misuse and dependence?

What is the best response to deal with the problem of barriers to treatment, particularly waiting lists, excessive waiting times and inflexible service hours?

What treatment needs exist in specific groups such regional and rural Victorians and Indigenous and culturally and linguistically diverse populations?

What are the needs of families and what are the best responses to these needs?

Is there a need to review and enhance the resources that are available to respond to benzodiazepine and narcotic analgesic misuse?

10. Concluding Remarks

This Interim Report has demonstrated the complexity of responding to the misuse and abuse of benzodiazepines and other forms of pharmaceutical drugs. The Inquiry has focussed on two major groups of drugs that are misused: benzodiazepines and narcotic analgesics. Each of these groups includes a range of different medications, with varying effects, prevalence of abuse and harms.

The Committee acknowledges that there are clear benefits associated with the safe and effective prescription and use of these drugs. However, evidence presented in this Interim Report has shown that there can be substantial harms for individuals, their families and the broader community if these drugs are not used safely and effectively and/or if they are intentionally misused. A major problem associated with pharmaceutical drug misuse is that many people in the community do not equate it with illegal or other harmful drug use. To some extent, compared to the attention given to illegal drugs, the issue has also been neglected by policymakers. As a result, the responses to the harms caused by pharmaceutical drug abuse have been inconsistent in terms of availability and quality.

The Committee has found that there are a variety of problems associated with pharmaceutical drug misuse. These include adverse physical and mental health consequences. For example, by ingesting these drugs in a mode that was not intended, such as by injection, there is a risk of a range of vascular damage and other serious health consequences. Moreover, combined with other drugs (such as heroin) the risks, especially the risk of overdose, are substantially increased. The Committee has also noted that there are dangers to community safety from impaired driving and increased risk of aggression and violence associated with these drugs.

A range of legislative responses, regulations and practice guidelines have been developed and implemented that directly and indirectly aim to ensure quality prescription, dispensing and use of medicines and to prevent pharmaceutical misuse. Other responses have included prevention and information strategies, legal and regulatory reform, policing initiatives and new treatment services.

For example, information/advisory and monitoring services have been developed to try to reduce 'doctor shopping/prescription shopping'. A range of

information and education programmes have been developed for patients, the general community and professional groups. The police respond to prescription forgery, drug diversion and sales, and the consequences of pharmaceutical misuse, such as the increased risk of aggression and impaired driving. The prison services have aimed to effectively manage prisoners who are dependent on a range of drugs, including pharmaceuticals, and prevent misuse within the prison system. Professional boards and organisations have identified quality use of medicines and prevention of pharmaceutical misuse as key issues and address these in newsletters, unambiguous standards of practice and practice guidelines, learning objectives and training programmes. Some pharmaceutical companies have attempted to address the issue by supporting the development and implementation of information and training programmes. The research and development units of some pharmaceutical companies have also sought to minimise the harms associated with certain prescription drugs by changing or adapting their chemical or pharmacological formulations. Various treatment services have also developed services and responses that are either directly or indirectly relevant to pharmaceutical misuse.

Nevertheless, despite such valuable efforts, pharmaceutical misuse continues to contribute to significant harm in the community. There are many issues pertaining to pharmaceutical drug misuse/abuse that this Committee believes need to be explored in greater detail. The complexity of these issues has not been able to be canvassed sufficiently in an Interim Report of this nature. For this reason the Committee believes it is essential that the Drugs and Crime Prevention Committee should undertake ongoing work in this area. The Committee therefore makes the following recommendation:

The Committee recommends, that due to the complexity and breadth of issues raised from the Committee's research and deliberations, the Inquiry into the Misuse/Abuse of Benzodiazepines and Other Forms of Pharmaceutical Drugs in Victoria be completed by the Drugs and Crime Prevention Committee of the 56th Parliament. In particular the Committee should focus on the findings and issues highlighted in the Interim Report.

To assist in conducting such an ongoing Inquiry and presenting a Final Report, the Committee has identified some areas that require further review and which should be included in the research brief of the new Inquiry. These include the following.

Issues highlighted in the Interim Report

The need to engage a wide range of stakeholders

There is a wide range of stakeholders who have a role in preventing and responding to pharmaceutical misuse. Pharmacists, medical practitioners and nurses readily come to mind. However, effective responses will also involve, for example, the police, consumer groups, local governments, hospitals, needle and syringe programmes, drug specialist services, the pharmaceutical industry, coroners, legislators and those responsible for monitoring pharmaceutical use. While it is evident that a number of these groups have developed responses that are consistent with quality practice, there is little evidence of coordination across the various sectors. It may be worthwhile exploring strategies to enhance coordination of prevention, harm reduction, treatment and other responses.

The need for coordinated responses

As already noted, there is a range of stakeholders across professional groups and across Commonwealth, state and local governments. It will be important to review current systems that aim to prevent and respond to pharmaceutical misuse and to assess where there can be improvements in coordination so that more effective prevention and other responses can be implemented. This will include a focus on legislative and regulatory approaches and information and monitoring systems. In addition, it will be important to review coordination of effort across professional groups in Commonwealth, state and local governments and the private sector. Consideration should be given to the creation of more uniform systems of management and monitoring of pharmaceutical use and misuse.

The need to manage the tension between the benefits and costs of the use and misuse of benzodiazepines and other forms of pharmaceutical drugs

Throughout the Inquiry it was apparent that any effective responses to pharmaceutical misuse must carefully address the tension between the benefits of safe and effective use of these drugs and the risks of misuse. It is imperative that any future interventions developed to address pharmaceutical drug *abuse* do not negatively impact on those people who are using these drugs for legitimate purposes.

The need to inform the broad community and patients about the risks of pharmaceutical misuse

In preparing this Interim Report, it was apparent that a barrier to effective intervention, at individual and community levels, was the perception by many that pharmaceutical misuse was not a major concern, and was not equivalent to other forms of drug dependence. It will be important to consider strategies to respond to this misperception, as it has implications for the implementation of effective prevention and treatment strategies.

The need to review the effectiveness of regulations, practice guidelines and compliance measures

The Inquiry identified that within Victoria, and across Australia, there has been substantial investment in the development of regulations, policies, practice guidelines and training materials. Professional boards such as the Nurses Board of Victoria, the Medical Practitioners Board of Victoria and the Pharmacists Board of Victoria have developed unambiguous and well publicised guidelines on expected standards of practice, both general and specifically relating to the drugs considered by this Inquiry. The Boards can legitimately investigate and respond to non-compliance by members of their respective professions. Medicare Australia also has relevant procedures. However, the adequacy and effectiveness of these strategies to ensure compliance have not been formally and/or thoroughly evaluated. Compliance strategies may be wanting, in terms of appropriateness, adequacy, resources and/or other factors. When research has been conducted on the value of clinical guidelines, for example, it is evident that they are not always used and not always sufficient to ensure quality practice. It will be worthwhile to review and consider formal evaluation of these critical components of quality practice and, based on this evidence, adapt current procedures and/or develop new ones.

The need to review the procedures for new formulations and examine the value of reformulating some medicines

Pharmaceutical companies are constantly developing new formulations of drugs, to enhance effectiveness and reduce side effects. In some countries, systems are being developed to ensure that any deleterious and unintended consequences do not increase the potential for misuse and/or increase the risks associated with that misuse. It will be useful to consider the value and practicality of such a system in Australia. Pharmaceutical companies have also re-formulated medicines to reduce their abuse potential. It will be valuable to examine the potential of such strategies.

The need to consider drug formulations that may reduce the risk of diversion and misuse

Combining one drug with another has been used to reduce diversion and misuse. In particular, this strategy has been employed with buprenorphine that is prescribed for the treatment of drug dependence. For example, as discussed in Chapter 8, a pharmaceutical company recently introduced a combination medication of buprenorphine and naloxone. When taken as intended (sublingually) the medication has the desired/intended treatment effect. If a dependent drug user injects the medication, the naloxone can result in unpleasant withdrawal symptoms. The value of this combined medication should be reviewed and carefully monitored. In the United States it has been suggested that this approach should be considered for other narcotic analgesics that are subject to diversion and misuse. It is important to stress that there is still the potential for diversion and misuse of such combination drugs, however

such a measure may reduce their attractiveness and currency among dependent drug users.

Misuse of some drugs has resulted in reformulations that reduced the risk of such misuse, for example by adding dyes, reducing access to formulations that have high abuse potential, or creating formulations that otherwise reduce the abuse potential of a drug. Such options should be further considered to gauge their applicability in the Victorian context.

The need to consider the training, accreditation, supervision and monitoring of health professionals

While there is a wide range of professional development programmes that have direct relevance to this issue, it would be worth considering these in the context of a detailed review of benzodiazepine and other forms of pharmaceutical drug misuse. Of particular interest will be the penetration of such programmes across professional groups (as opposed to marginal uptake by a minority of the relevant professions) and evidence of their impact on quality practice. Similarly, while there are a number of compliance strategies that can be used to ensure standards of practice, it will be important to review their adequacy in terms of the dedicated resources and impact.

The need to review the current scheduling of some benzodiazepines

Pharmaceutical misuse can be affected by prescription controls, particularly the scheduling of a drug. Re-scheduling has been used as a strategy in a number of countries, including Australia. In Australia, for example, flunitrazepam was re-scheduled from a S4 to S8 drug. This has been associated with a reduction in use, misuse and related harm. Some of those who made submissions to the Inquiry argued for a review of the regulatory status of benzodiazepines, recommending that some or all of these drugs should be re-scheduled. Others argued that some caution should be exercised, so as not to diminish access to those who are in 'genuine need' of such pharmacotherapies. It will be worthwhile to explore further this potential strategy.

The need to identify the sources of misused pharmaceuticals to ensure informed and effective responses

Pharmaceutical drugs may be obtained from various sources, such as prescription forgery or 'doctor/prescription shopping', from the black market, from the Internet, or from a friend or member of the family. Different strategies will be required to respond to each source.

The need to review the current and potential influence of the Internet on pharmaceutical misuse

The Internet is a relatively new source of legitimate and illicit pharmaceutical drugs. The Internet is also a potential source of information and advice that might be used to prevent and respond to pharmaceutical misuse. The relative recency of this source of medication and information about drug use means

that there is limited evidence about its impact. It will be worth considering this issue in further detail in the ongoing work of the Inquiry.

The need for effective information and monitoring systems

Quality information and monitoring systems were identified as critical in the development of a range of effective strategies to help prevent and reduce pharmaceutical misuse. Such systems ideally should:

- Identify community wide patterns of pharmaceutical drug use and misuse;
- Assist in ensuring quality prescribing and dispensing practices;
- Assist in the implementation of effective compliance measures;
- Reduce intentional and inadvertent over-prescription;
- Identify individuals who are 'doctor/prescription shopping';
- Help in patient diagnosis and development of individual treatment plans;
- Assist in quality patient management;
- Assist in preventing diversion; and
- Contribute to effective monitoring and evaluation of other responses to pharmaceutical misuse.

Various individuals and organisations who made submissions to the Inquiry, including medical staff, regulators, pharmacists and relatives of someone who had experienced problems related to pharmaceutical misuse, made recommendations regarding the need to review and enhance information and monitoring systems. This issue has also been considered overseas, and a number of people who made submissions and presentations to the Inquiry identified the PharmaNet system in British Columbia as a good model. It is important that the value and practicality of such a model be considered as part of the deliberations of the new Inquiry.

The need for a range of harm reduction strategies

Even the best prevention and treatment strategies need to be accompanied by harm reduction strategies – some people will continue to divert and misuse these medications, potentially causing harm to themselves and other people. People who misuse such drugs can experience a range of harms, from increased risk of overdose, increased risk of aggression and violence, and increased risk of vascular injury and disease and other health problems. It will be important to review the adequacy of current harm reduction strategies and their application to those who misuse pharmaceutical drugs alone and in combination with other drugs. It is likely that a variety of media and outlet locations will be required for such strategies. While needle and syringe programmes, consumer organisations and drug treatment services are critical contributors to such approaches there will be many at-risk people who do not perceive these services as being valid to their needs. This might include those who see their

pharmaceutical misuse as being distinct from other harmful drug use, older patients, and some culturally and linguistically diverse groups. Therefore it will be important to review the nature of harm reduction strategies, the content of such strategies and the most appropriate modes of delivery to the various target groups.

The need to review access to treatment

A number of individuals and organisations that made a submission to the Inquiry noted that access to treatment should be reviewed. Several commented that there were waiting lists for treatment and that hours of service did not always match potential and actual need. It is important to note that current specialist drug services may not always be attractive to some individuals who misuse pharmaceuticals.

It was also noted that the treatment needs of specific groups should be reviewed, including:

- Young people;
- Parents;
- Culturally and linguistically diverse groups;
- People living in rural and regional Victoria;
- Prisoners;
- Older Victorians;
- Indigenous Australians; and
- People in the workplace.

The need to consider some specific consequences of the use and misuse of these drugs

The use and misuse of these drugs can result in specific consequences, and any preventive, harm reduction and treatment response should be considered in the context of these issues. For example, it will be important to consider:

- The protracted nature of benzodiazepine withdrawal. Several contributors to the Inquiry noted that the withdrawal syndrome for some benzodiazepines could be protracted, with implications for the duration and nature of management and treatment;
- The vascular and other damage that can arise from injecting drugs not designed to be ingested in this way;
- The risk of overdose (from the use and misuse of benzodiazepines and narcotic analgesics), especially when combined with other drugs; and
- The difficulty in managing other health problems in patients who are misusing/dependent on pharmaceutical drugs. For example, the challenge of managing sleep disorders in someone who is dependent on benzodiazepines, the emergence or re-emergence of anxiety disorders

when withdrawn from benzodiazepines and the challenge of managing pain in someone who is misusing narcotic analgesics.

The need to develop a system to manage people who are dependent on benzodiazepines and other forms of pharmaceutical drugs

Prescribing Schedule 8 drugs to treat people who are dependent on opioids (that is, prescribing buprenorphine and methadone) is carefully controlled. There are specific and unambiguous policies and guidelines, and prescribing and dispensing these medications for this purpose to a specific patient requires formal authority by the Department of Human Services. Such authorisation is dependent on acquiring the relevant expertise and operating in a manner that is consistent with accepted standards of safe and effective practice. This system aims to coordinate and ensure the provision of quality care to individual patients and reduce risks to these patients and the broader community. Some contributors to the Inquiry suggested that a similar system could be considered for the management of patients who are dependent on other drugs (that is, Schedule 4 drugs) that have been the focus of this Inquiry.

The need to review responses to drug-impaired driving

A proportion of people who drive while impaired by drugs have consumed benzodiazepines and/or narcotic analgesics, alone or in combination with other drugs. One challenge for the current systems that have been adopted to detect and deter drug-impaired driving is the difficulty in distinguishing between those who are using such medications legitimately, where careful clinical management reduces risk, and those who are misusing such drugs and whose capacity to drive safely will consequently be impaired. It will be important to review the potential impact of such use and to consider current approaches to detect and deter impairment.

The need to review information and education initiatives

There appears to be variable knowledge about the risks associated with misuse of pharmaceutical drugs. Many people in the broad community, among those who use benzodiazepines and narcotic analgesics and including those who misuse these drugs, are ignorant of or underestimate the risks. Although a number of organisations have developed and disseminate relevant information with regard to those drugs, there are some gaps in the information provided. It is apparent that a more systematic and coordinated approach is needed.

The need for more research

In the process of preparing this Interim Report, it was evident that there were gaps in the evidence base. It will be important to identify these gaps and to develop strategies to respond. The particular gaps that have been identified thus far include:

- Knowledge about the prevalence of misuse and harm among certain groups in the community (for example, Indigenous Australians, people

living in rural and regional locations, culturally and linguistically diverse groups);

- The impact of regulatory strategies and scheduling changes on pharmaceutical drug misuse and use of these drugs by people in 'genuine need';
- The most effective information and monitoring systems;
- Risk and protective factors for pharmaceutical misuse;
- The most effective methods to identify and diagnose pharmaceutical misuse;
- The most effective treatments for those who misuse and are dependent on benzodiazepines and narcotic analgesics; and
- The social contexts that contribute to increased risk of drug misuse and, conversely, those that support and sustain effective interventions.

Australia, and in particular Victoria, is not unique in facing these challenges. In a recent American review it was concluded that:

> If we are to curb this growing problem and curb its disastrous consequences, we must train doctors, pharmacists and other healthcare professionals to spot the problem and know how to respond; educate the public about risks; tailor prevention and intervention to the unique characteristics of abusers; and assure appropriate and accessible treatment.
>
> At the same time we must reduce availability by stopping the sale of controlled prescription drugs on the Internet, improving our ability to monitor diversion, cracking down on criminals and script doctors, enforcing drug importation laws, regulating advertising and marketing practices and reformulating drugs where possible to reduce their abuse potential. (Centre for Addiction and Substance Abuse 2005, p.99).

Conclusion

In conclusion, this Committee believes that due to the complexity and importance of the issues raised in this Interim Report, it is essential that the Drugs and Crime Prevention Committee of the 56th Parliament undertake further investigation with the aim of producing a Final Report into benzodiazepine and other pharmaceutical drug abuse.

The various chapters in this Interim Report resulted in some key questions that should be considered in more detail in subsequent work by the Drugs and Crime Prevention Committee.[414] The issues that require further investigation range from the skills that are needed by health care practitioners and pharmacists and the tools that are necessary to help them implement quality responses to pharmaceutical misuse, to the information and monitoring

414 These questions follow the discussion at the end of each chapter.

systems that will produce the best outcomes, while at the same time maintaining quality care for patients in 'genuine need'.

From a preliminary analysis it also seems apparent that further inquiry into the best models and systems of coordination that can be applied across all sectors to address prescription drug abuse is essential.

However, perhaps more than any other single issue, the most difficult of the challenges posed by this Inquiry is countering the perception that prescription drugs are somehow not 'drugs of abuse'. This is a belief not only of consumers of these drugs but also, if the evidence of the Inquiry is indicative, one shared by certain prescribers of these drugs. As this Committee discovered during the deliberations for its previous Inquiry into Alcohol Abuse in Victoria, challenging the culture of drug use and abuse, indeed contesting ideas as to what does or does not count as a 'drug', is a very difficult task. Alcohol and 'pills', it would seem, simply are not viewed with the same gravity as heroin or 'designer' drugs.

Appendices

Appendix 1: List of Submissions Received

Submission Number	Name of Individual/Organisation	Date Received
1	Mr Leon Hain	3 April 2006
2	Confidential Submission	24 April 2006
3	Ms Sue White Manager, Access Health Salvation Army Crisis Centre	2 May 2006
4	Mr David Murray Chief Executive Officer Youth Substance Abuse Service (YSAS)	5 May 2006
5	Confidential Submission	5 May 2006
6	Dr Frank Giorlando Addiction Medicine Registrar Interhospital Liaison Group, Southern Health	5 May 2006
7	Dr Mark Stoove, Research Fellow Ms Rebecca Jenkinson, Research Fellow Turning Point Alcohol and Drug Centre	5 May 2006
8	Ms Carol Andrew Psychiatric Nurse Moreland Continuing Care Program, NW Mental Health Program	10 May 2006
9	Ms Sue Morrell Group Manager, Community Services City of Melbourne	13 June 2006
10	Ms Gwenda Cannard Director TRANX Inc.	16 June 2006
11	Mr Colin Bridge A/g General Manager Program Review Division, Medicare Australia	19 June 2006
12	Mr Michael Burt Chief Executive Officer Forensicare, Victorian Institute of Forensic Mental Health	19 June 2006
13	Ms Rosemary McClean Policy and Program Adviser Australian Drug Foundation	19 June 2006

Submission Number	Name of Individual/Organisation	Date Received
14	Mr Stephen Marty Registrar Pharmacy Board of Australia	19 June 2006
15	Mr John Ilott Chief Executive Officer Pharmaceutical Society of Australia (Vic)	19 June 2006
16	Mr George Mavroyeni General Manager, Road Safety VicRoads	19 June 2006
17	Confidential	20 June 2006
18	Mr John Ryan Chief Executive Officer Anex	22 June 2006
19	Ms Margaret Quon	23 June 2006
20	Ms Louise Milne-Roch Chief Executive Officer Nurses Board of Victoria (NBV)	28 June 2006
21	Ms Lydia Wilson Chief Executive Officer City of Yarra	29 June 2006
22	Judge Paul Grant President Children's Court of Victoria	4 July 2006
23	Ms Sharon Read General Manager Primary Care and Information Management Western Region Health Centre	5 July 2006
24	Dr Paul Woodhouse Director of Policy Australian Medical Association (Victoria) Limited (AMA)	7 July 2006
25	Professor Olaf Drummer Head (Forensic and Scientific Services) Victorian Institute of Forensic Medicine	20 July 2006
26	Dr Rodger Brough Drug and Alcohol Physician Western Region Alcohol and Drug Centre (WRAD)	21 July 2006
27	Mr Mark Boyd Community Health and Safety Project Coordinator Darebin City Council	25 July 2006
28	Dr Nick Carr St Kilda Medical Group	26 July 2006

Appendix 2: Witnesses Appearing at Public Hearings

Hearings in Melbourne – 19 June 2006

Name	Position	Organisation
Mr George Mavroyeni	General Manager, Road Safety	VicRoads
Dr Philip Swann	Manager, Drugs, Fatigue and Alcohol	VicRoads
Ms Ros Burnett	Clinical Nurse Consultant	Interhospital Liaison Group
Dr Matthew Frei	Addiction Medicine Physician	Interhospital Liaison Group
Dr Frank Giorlando	Addiction Medicine Registrar	Interhospital Liaison Group
Mr John Ilott	Chief Executive Officer	Pharmaceutical Society of Australia (Vic)
Mr Irvine Newton	Chairman, Harm Minimisation Committee	Pharmaceutical Society of Australia (Vic)
Mr Dipak Sanghvi	President	Pharmacy Guild (Victorian Branch)
Mr Maurice Sheehan	Director	Pharmacy Guild (Victorian Branch)
Ms Gwenda Cannard	Director	TRANX
Ms Julie Harrick	Manager	Transport Accident Commission (TAC)
Dr Peter Harcourt	Chief Health Officer	Transport Accident Commission (TAC)
Mr Steve Marty	Registrar	Pharmacy Board

Hearings in Melbourne – 20 June 2006

Name	Position	Organisation
In Camera	-	-
Mr John Ryan	Chief Executive Officer	Anex
Dr Mike McDonough	Medical Director, Drug and Alcohol Services	Western Hospital
Mr David Murray	Chief Executive Officer	Youth Substance Abuse Service (YSAS)
Mr Tony Palmer	Trainer and Consultant	Youth Substance Abuse Service (YSAS)

Hearings in Melbourne – 13 July 2006

Name	Position	Organisation
Professor Olaf Drummer	Head (Forensic and Scientific Services)	Victorian Institute of Forensic Medicine (VIFM)
Dr Mike McDonough	Medical Director, Drug and Alcohol Services	Western Hospital

Appendix 3: Demand Reduction Glossary of Terms

- ***Abuse***: "A term in wide use but of varying meaning. In international drug control conventions 'abuse' refers to any consumption of a controlled substance no matter how infrequent. In the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, American Psychiatric Association 1994), 'psychoactive substance abuse' is defined as "a maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one (or more) of the following within a 12 month period: (a) recurrent substance use resulting in a failure to fulfil major role obligations at work, school or home; (b) recurrent substance use in situations in which it is physically hazardous; (c) recurrent substance-related legal problems; (d) continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance" (United Nations International Drug Control Program, 2000, p.1).
- ***Addiction, addict:*** One of the oldest and most commonly used terms to describe and explain the phenomenon of long-standing drug abuse. In some professional circles it has been replaced by the term 'drug dependence'. According to the WHO Lexicon of Alcohol and Drug Terms, addiction is defined as: the repeated use of a psychoactive substance or substances, to the extent that the user (referred to as an addict) is periodically or chronically intoxicated, shows a compulsion to take the preferred substance (or substances), has great difficulty in voluntarily ceasing or modifying substance use, and exhibits determination to obtain psychoactive substances by almost any means. … In the 1960s the WHO recommended that the term 'addiction' be abandoned in favour of dependence, which can exist in various degrees of severity as opposed to an 'all or nothing' disease entity. Addiction is not a diagnostic term in the ICD-10, but continues to be very widely employed by professionals and the general public alike (United Nations International Drug Control Program 2000, pp.2–3).
- ***Dependence, dependence syndrome*:** According to the WHO Lexicon of Alcohol and Drug Terms, dependence, dependence syndrome is defined as: as applied to alcohol and other drugs, a need for repeated doses of the drug to feel good or to avoid feeling bad. The terms 'dependence' and 'dependence syndrome' have gained favour with WHO and in other circles as alternatives to 'addiction' since the 1960s. Their use was recommended as an acknowledgment of new evidence that 'addiction' was not a discrete disease entity but could exist in degrees, as indeed could its constituent

signs. For example, 'loss of control' over drug use was replaced with 'impaired control'. In the DSM-IV, dependence is defined as "a cluster of cognitive, behavioural and physiological symptoms indicating that the individual continues use of the substance despite significant substance-related problems" (United Nations International Drug Control Program 2000, p.19).

- ***Detoxification*:** The process by which a person who is dependent on a psychoactive substance ceases use, in such a way that minimizes the symptoms of withdrawal and risk of harm. While the term 'detoxification' literally implies a removal of toxic effects from an episode of drug use, in fact it has come to be used to refer to the management of rebound symptoms of neuroadaptation, i.e. withdrawal and any associated physical and mental health problems. The facility in which the procedure takes place is usually called a detoxification centre. Traditionally detoxification has been provided on an in-patient basis either in a specialist treatment facility or on the wards of a general or psychiatric hospital. There is an increasing trend to provide detoxification services in informal settings including the clients' own homes. Home-based detoxification usually involves visiting medical staff and informal support provided by family or friends. As a clinical procedure, detoxification is undertaken with a degree of supervision. Typically, the individual is clinically intoxicated or already in withdrawal at the outset of detoxification. Detoxification may involve the administration of medication. When it does, the medication given is usually a drug that shows cross-tolerance and cross-dependence to the substance(s) taken by the patient. The dose is calculated to relieve the withdrawal syndrome without inducing intoxication, and is gradually tapered off as the patient recovers. Detoxification as a clinical procedure implies that the individual is supervised until recovery is complete, both from intoxication and physical withdrawal (United Nations International Drug Control Program 2000, pp.20–21).

- ***Half-life:*** The term refers to the time needed for the blood level of a particular drug to decline to half of the maximum level (peak). After absorption, the various drugs are transported to the various sites of action through the blood stream. During this transportation and distribution process, the drugs already in the blood or in the various organs are gradually transformed into various metabolites, and either deposited or excreted from the body. All these processes proceed parallel. The metabolic process of drugs usually involves several stages and transformation steps, usually performed by specific body enzymes. The rate of metabolism at each stage varies from substance to substance and between individuals, as influenced by several internal and external factors. Different drugs are distributed and metabolized through quite different routes and the blood level of each drug as a function of time tends to be substance-characteristic. Half-life is a generally accepted characteristic value in comparing the

metabolic and pharmacological characteristics of various drugs. It is an indication of the relative duration of a drug's effects. Heroin, for example, has a short half-life, while morphine has a longer one. The various benzodiazepines and barbiturates also have greatly varying half-lives (United Nations International Drug Control Program 2000, p.30).

- ***Illicit Use***: Illicit use is defined as use of medication that was not obtained on prescription in the individual's name (Stafford, Degenhardt, Black et al. 2006).
- ***Misuse:*** According to the WHO Lexicon of Alcohol and Drug Terms, misuse is defined as: the use of a substance for a purpose not consistent with legal or medical guidelines, as in the non-medical use of prescription medications. The term is preferred by some to 'abuse' in the belief that it is less judgmental. It may also refer to high-risk use, e.g. excessive use of alcohol in situations where this is not illegal (United Nations International Drug Control Program 2000, p.45).
- ***Tolerance:*** A term for the well-established phenomenon of reduced drug effects following repeated drug administrations. Tolerance develops fastest with more frequent episodes of use and with larger amounts per occasion. It is useful to distinguish between metabolic tolerance and functional tolerance. Metabolic tolerance arises usually as a consequence of an induction of liver enzymes which result in the faster metabolism of a given drug dose, thereby reducing the level and duration of blood-drug levels. Functional tolerance refers to diminished effects of a given blood-drug level. This is thought to occur both by virtue of neuroadaptation, as well as by the user learning to anticipate and accommodate intoxicating effects (United Nations International Drug Control Program 2000, p.71).
- ***Withdrawal:*** A term used to refer to either the individual symptoms of, or the overall state (or syndrome), which may result when a person ceases use of a particular psychoactive drug upon which they have become dependent or after a period of repeated exposure. The level of central nervous system arousal and the accompanying mood state is usually directly opposite to the direct action of the drug. Thus withdrawal from central nervous system depressants typically involves increased anxiety and heightened arousal level (increased heart rate, blood pressure and perspiration). Withdrawal from central nervous system stimulants involves reduced arousal, lethargy and depression. Withdrawal states and symptoms exist in degrees as a direct consequence of the frequency, intensity and recency of drug use. Withdrawal or 'rebound' phenomena have been demonstrated after relatively brief periods of heavy drug use for a wide range of drug types and are not experienced exclusively by severely dependent individuals (United Nations International Drug Control Program 2000, p.75).

Bibliography

Abreu, ME. Bigalow, GE, Fleisher, L & Walsh, SL. 2001, 'Effect of intravenous injection speed on responses to cocaine and hydromorphone in humans', *Psychopharmacology*, vol. 154, pp.76–84.

Alder, C & Read, H 1992, *The re-integration problems of drug using young offenders,* Monograph Series no. 23, National Campaign Against Drug Abuse, Commonwealth of Australia, Canberra.

Alford, C & Vester, J 2005, 'NICE review: Not nice for patients!', *Psychopharmacology*, vol. 19, no. 2, pp.129–132.

Ali, R, Biggs, L, Gill, T, Larkins, K, Moyle, K, Murray, T, Perrin, J, Quigley, A, Rysavy, P, Sujic, S, Wilson, C & Richards, I 2001 *National buprenorphine policy*, National Drug Strategy, Department of Health and Aged Care, Canberra.

Allsop, S 2000, Effective treatment, unpublished paper, Next Step Specialist Drug and Alcohol Services and Curtin University of Technology, Perth WA.

Allsop, S, Bell, J, Brough, R, Dwyer, P, Edmonds, C, Lintzeris, N & Mohindra, V 1997, *Learning objectives for methadone prescribers*, Australian Government Publishing Service, Canberra.

Allsop, S & Helfgott, S 2002, 'Whither the drug specialist? The work-force development needs of drugs specialist staff and agencies', *Drug and Alcohol Review*, vol. 21, pp.215–222.

Allsop, S, Corry, C & Ernst, L 2004, *National learning objectives and assessment procedures for the pharmacological management of opioid dependence*, Publications Production Unit, Australian Government Department of Health and Ageing, Canberra.

Ashton, H 2002, 'Benzodiazepines: How they work and how to withdraw', *Neurology, Neurobiology and Psychiatry*, University of Newcastle, Newcastle. (Available at: http://benzo.org.uk/manual/index.htm).

Ashworth, M, Gerada, C & Dallmeyer, R 2002, 'Benzodiazepines: addiction and abuse', *Drugs: Education, prevention and policy*, vol. 9, no. 4, pp.389–97.

Australian Centre for Policing Research 2002, *The diversion of pharmaceutical drugs onto the illicit drug market,* Australian Centre for Policing Research, Marden.

Australian Crime Commission (ACC) 2006, *Australian Illicit Drug Report 2004-05*, ACC, Canberra.

Australian Drug Foundation (ADF) 2006, ADF website. (Accessed at: http://druginfo.adf.org.au/article.asp?ContentID=benzodiazepines).

Australian Health Ministers' Advisory Council (AHMAC) 2003, *Working party response to the review of Drugs, Poisons and Controlled Substances legislation* (the Galbally Review), AHMAC, Canberra. June 2003.

Australian Illicit Drug Report 1997–98

(Accessed at: http://www.crimecommission.gov.au/content/publications/aidr_1999/07_Other_drugs.pdf).

Australian Institute of Health and Welfare (AIHW) 1999, *1998 National drug strategy household survey: First results*, cat. no. PHE 15, AIHW, Canberra.

Australian Institute of Health and Welfare (AIHW) 2002, *2001 National drug strategy household survey: Detailed findings*, cat. no. PHE 41, AIHW, Canberra.

Australian Institute of Health and Welfare (AIHW) 2005a, *2004 National drug strategy household survey: Detailed findings*, cat. no. PHE 66 (Drug Statistics Series No. 16), AIHW, Canberra.

Australian Institute of Health and Welfare (AIHW) 2005b, *2004 National drug strategy Household survey: First results*, cat. no. PHE 57 (Drug Statistics Series No. 13), AIHW, Canberra.

Australian Institute of Health and Welfare (AIHW) 2005c, *2004 National drug strategy household survey: State and territory supplement*, cat. no. PHE 61, AIHW, Canberra.

Banta, C 2005, 'Trading for a high', *TIME Magazine*, August, p.35. (Accessed 21 July 2006 at: http://www.time.com/time/archive/preview/0,10987,1086173,00.html).

Barker, M, Jackson, M, Geenwood, K & Crowe, S 2003, 'Cognitive effects of benzodiazepine use: A review', *Australian Psychologist*, vol. 38, no. 3, 202–213.

Baume, P 1991, *A question of balance: Report on the future of drug evaluation in Australia*, Australian Government Publishing Service (AGPS), Canberra.

Ben-Porath, D & Taylor, S 2002, 'The effects of diazepam (valium) and aggressive disposition on human aggression: An experimental investigation', *Addictive Behaviors*, vol. 27, no. 2, pp.167–177.

Bird, S 2006, 'Prescribing schedule 8 drugs', *Australian Family Physician*, vol. 35, no. 1 / 2, January/February, pp.59–60.

Bliding, A 1974, 'Effects of different rates of absorption of two benzodiazepines on subjective and objective parameters. Significance for clinical use and risk of abuse', *European Journal of Clinical Pharmacology*, vol. 7, pp.201–211.

Blumenschein, K 1997, 'Prescription drug diversion: Fraudulent tactics utilized in the community pharmacy', *American Journal of Pharmaceutical Education*, vol. 61, pp.184–188.

Breen, C, Degenhardt, L, Roxborgh, A, Bruno, R, Duquemin, A, Fetherston, J, Fischer, J, Jenkinson, R, Kinner, S, Longo, M & Rushforth, C 2003, *Australian drug trends 2002: Findings from the Illicit Drug Reporting System (IDRS)*, Monograph no. 50, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney.

Breen, C, Degenhardt, L, Bruno, R, Roxburgh, A & Jenkinson, R 2004, 'The effects of restricting publicly subsidised temazepam capsules on benzodiazepine use among injecting drug users in Australia', *Medical Journal of Australia*, vol. 181, no. 6, pp.300–304.

Breen, C, Degenhardt, L, Roxborgh, A, Bruno, R, Fetherston, J, Jenkinson, R, Kinner, S, Moon, C, Proudfoot, P, Ward, J & Weekley, J 2004, *Australian drug trends 2003: Findings from the Illicit Drug Reporting System (IDRS)*, Monograph no. 51, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney.

Brushwood, DB & Kimberlin, CA 2004, 'Media coverage of controlled substance diversion through theft or loss', *Journal of the American Pharmacists Association*, vol. 44, no. 4, pp.439–444.

Busto, UE & Sellers, EM 1986, 'Pharmacokinetic determinants of drug abuse and dependence. A conceptual perspective', *Clinical Pharmacokinetics*, vol. 11, pp.144–153.

Busto, UE, Romach, MK & Sellers, EM 1996, 'Multiple drug use and psychiatric comorbidity in patients admitted to the hospital with severe benzodiazepine dependence', *Journal of Clinical Psychopharmacology*, vol. 16, no. 1, pp.51–57.

Butterworth, T 2004, 'The New York Times' other WMD problem', *STATS at George Mason University*, 6 August. (Accessed 20 July 2006 at: http://www.stats.org/stories/2004/NYT_other_wmd_aug06_04.htm)

Caplehorn, J, Robertson, MD & Swann, P 2003, 'The involvement of drugs in drivers of motor vehicles killed in Australian road traffic crashes', *Accident Analysis & Prevention*, vol. 943, pp.1–10.

Carr, N 2000, 'I just want some Valium, Doc', *RACGPOnline* (The Royal Australian College of General Practitioners). (Accessed at: http://www.racgp.org.au/document.asp?id=1916).

Carruthers, S 2003, 'The ins and outs of injecting in Western Australia', *Journal of Substance Use*, vol. 8, no.1, pp.11–19.

Chivite-Matthews, N, Richardson, A, O'Shea, J, Becker, J, Owen, N, Roe, S & Condon, J 2005, *Drug misuse declared: Findings from the 2003/04 British Crime Survey – England and Wales*, Home Office, London. (Accessed at http://www.homeoffice.gov.uk/rds/bcs1.html).

Cicero, TJ, Inciardi, JA & Munoz, A 2005, 'Trends in abuse of OxyContin® and other opioid analgesics in the United States: 2002–2004', *The Journal of Pain*, vol. 6, no. 10, pp.662–672.

Clark, N, Lintzeris, N & Muhleisen, P 2002, 'Severe opiate withdrawal in a heroin user precipitated by a massive buprenorphine dose', *Medical Journal of Australia*, vol. 176, no. 4, pp.166–167.

Clow, B 2003, 'An illness of nine months duration: Pregnancy and thalidomide use in Canada and the United States', in GD Feldberg (ed.), *Women, health and nation: Canada and the United States since 1945*, McGill-Queens University Press, Montreal and Kingston, pp.45–66.

Compton, WM & Volkow, ND 2006, 'Major increases in opioid analgesic abuse in the United States: Concerns and strategies', *Drug and Alcohol Dependence*, vol. 81, pp.103–107.

Cone, EJ 2006, 'Ephemeral profiles of prescription drug formulation and tampering: Evolving pseudoscience on the internet', Supplement, *Drug and Alcohol Dependence*, vol. 83, pp.31–39.

Dabney, DA & Hollinger, RC 2002, 'Drugged druggists: The convergence of two criminal career trajectories', *Justice Quarterly,* vol. 19, no. 1, p.181.

Daderman, A & Edman, G 2001, 'Flunitrazepam abuse and personality characteristics in male forensic psychiatric patients', *Psychiatry Research*, vol. 103, no. 1, pp.27–42.

Darke, S, Swift, W, Hall, W & Ross, M 1993, 'Drug use, HIV risk-taking and psychosocial correlates of benzodiazepine use among methadone maintenance clients', *Drug and Alcohol Dependence*, vol. 34, pp.67–70.

Darke, S & Zador, D 1996, 'Fatal heroin "overdose": A review', *Addiction*, vol. 91, pp.1765–1772.

Darke, S, Ross, J & Hall, W 1996, 'Overdose among heroin users in Sydney, Australia: Prevalence and correlates of non-fatal overdose', *Addiction*, vol. 91, pp.405–411.

de Crespigny, C & Wodak, A 1995, *Drug and Alcohol Review 1995*, (*News and Views*), vol. 14, p.139.

Degenhardt, L, Day, C, Dietze, P, Pointer, S, Conroy, E, Collins, L & Hall, W 2005, 'Effects of a sustained heroin shortage in three Australian States', *Addiction*, vol. 100, no. 7, pp.908–920.

de las Cuevas, C, Sanz, E & de la Fuente, J 2003, 'Benzodiazepines: More behavioural "addiction" than dependence', *Psychpharmacology*, vol. 167, pp.297–303.

Department of Health (England) 2001, *Prescription cost analysis: England 2000*, National Statistics, Government Statistical Service, London.

Department of Health (England) 2002, *Prescription cost analysis: England 2001*, National Statistics, Government Statistical Service, London.

Department of Health (England) 2003, *Prescription cost analysis: England 2002*, National Statistics, Government Statistical Service, London.

Department of Health (England) 2004, *Prescription cost analysis: England 2003*, National Statistics, Government Statistical Service, London.

Department of Health (England) 2005, *Prescription cost analysis: England 2004*, National Statistics, Government Statistical Service, London.

Department of Health (England) 2006, *Prescription cost analysis: England 2005*, National Statistics, Government Statistical Service, London.

Department of Health and Ageing (DoHA) (Commonwealth) 1999, *National medicines policy 2000*, Australian Government, Canberra. (Accessed at: http://www.health.gov.au/internet/wcms/publishing.nsf/content/nmp-pdf-nmp2000-cnt.htm).

Department of Health and Ageing (DoHA) 2000, *National medicines policy*, DHA, Australian Government, Canberra. (Accessed at: http://www.health.gov.au/pbs/natmedpol.htm).

Department of Health and Ageing (DoHA) (Commonwealth) 2004, *National strategy for the quality use of medicines*, DoHA, Australian Government, Canberra. (Accessed at: http://www.health.gov.au/internet/wcms/publishing.nsf/content/nmp-pdf-natstrateng-cnt.htm).

Department of Health and Ageing (DoHA) (Commonwealth) 2005a, *Australian pharmaceutical advisory council*, DoHA, Australian Government, Canberra. (Accessed at: (http://www.health.gov.au/internet/wcms/publishing.nsf/content/nmp-advisory-apac.htm).

Department of Health and Ageing (DoHA) (Commonwealth) 2005b, *Quality use of medicines*, DoHA, Australian Government, Canberra. (Accessed at: http://www.health.gov.au/internet/wcms/publishing.nsf/content/nmp-quality.htm).

Department of Health and Ageing (DoHA) (Commonwealth) 2006a, *Pharmaceutical benefits scheme*, DoHA, Australian Government, Canberra. (Accessed at: (http://www.health.gov.au/internet/wcms/publishing.nsf/content/pharmaceutical%20benefits%20scheme%20(pbs)-2).

Department of Health and Ageing (DoHA) (Commonwealth) 2006b, *Therapeutics goods administration (TGA)*, DoHA, Australian Government, Canberra. (Accessed at: http://www.tga.gov.au/docs/html/tga/tgaginfo.htm).

Department of Health and Ageing (DoHA) (Commonwealth) 2006c, *Schedule of pharmaceutical benefits – 1 April 2006*, DHA, Australian Government, Canberra. (Accessed at: http://www.health.gov.au/internet/wcms/publishing.nsf/content/pbs-schedule-authority).

Department of Human Services (DHS) Victoria 2002, *Drugs: How and where to get help*, DHS, Melbourne. (Accessed at: www.drugs.vic.gov.au).

Department of Human Services (DHS) Victoria 2004, *Victorian secondary school students' use of licit and illicit substances in 2002 – Results from the 2002 Australian Secondary Students' Alcohol and Drug Survey*, DHS, Melbourne.

Department of Human Services (DHS) Victoria 2006a, *Guide to the drugs, poisons and controlled substances regulations 2006*, DHS, Melbourne.

Department of Human Services (DHS) Victoria 2006b, *Key prescribing requirements for medical practitioners 2006*, DHS, Melbourne.

Department of Human Services (DHS) Victoria 2006c, *Obtaining information about drug-seeking patients*, DHS, Melbourne.

Department of Human Services (DHS) Victoria 2006d, *Policy for maintenance pharmacotherapy for opioid dependence*, DHS, Melbourne.

Department of Human Services (DHS) Victoria 2006e, *The Victorian drug statistics handbook 2005: Patterns of drug use and related harm in Victoria*, Victorian Government Publishing Service, Melbourne.

Department of Human Services (DHS) Victoria 2006f, *Approved by the secretary*, crcular, DHS (Drugs and Poisons Unit), Melbourne. (Accessed 3 July 2006 at: www.health.vic.gov.au /dpu/approve.htm.

Department of Human Services (DHS) Victoria 2006g, *Managing dugs in gneral pactice*, circular, DHS, Melbourne. (Accessed at: http://www.health.vic.gov.au/dpu/).

Department of Human Services (DHS) Victoria 2006h, *Interventions by pharmacists*, circular, DHS, Melbourne. (Accessed at: http://www.health.vic.gov.au/dpu/).

Dietze, P, Miller, P, Clemens, S, Matthews, S, Gilmour, S & Collins, L 2004, *The course and consequences of the heroin shortage in Victoria*, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney.

Dinwiddie, S, Cottler, L, Compton, W & Abdullah, A 1996, 'Psychopathology and HIV risk behaviours among injecting drug users in and out of treatment', *Drug and Alcohol Dependence*, vol. 43, pp.1–11.

Dobbin, M 2001, 'Temazepam injection in Victoria', Unpublished discussion paper, Department of Human Services (Victoria), Melbourne.

Dobbin, M 2006a, 'Temazepam injection in Australia, 2000–2004', Unpublished internal paper, Department of Human Services (Victoria), Melbourne.

Dobbin, M 2006b, 'Morphine', Unpublished paper provided to the Drugs and Crime Prevention Committee.

Dobbin, M 2006c, 'Oxycodone', Unpublished paper provided to the Drugs and Crime Prevention Committee.

Dobbin, M 2006d, 'Methadone', Unpublished paper provided to the Drugs and Crime Prevention Committee.

Dobbin, M 2006e, 'Buprenorphine', Unpublished paper provided to the Drugs and Crime Prevention Committee.

Dobbin, M, Martyres, RF, Clode, D & Champion de Crespigny, FE 2003, 'Association of benzodiazepine injection with the prescription of temazepam capsules', *Drug and Alcohol Review*, vol. 22, pp.153–157.

Doctors Health Database (Victoria), Australian Medical Council website. (Accessed 6 July 2006 at: http://www.ama.com.au/web.nsf/doc/WEEN-5NE979).

Downie, G &, Kettle, J 2000, 'The abuse and misuse of prescribed and over-the-counter medicines', *Hospital Pharmacist*, vol. 7, pp.242–50.

Drug Utilisation Sub-Committee 2003, *Australian statistics on medicines 1999–2000*, Commonwealth Department of Health and Ageing, Australian Government, Canberra.

Drug Utilisation Sub-Committee 2004, *Australian statistics on medicines 2001–2002*, Department of Health and Ageing, Australian Government, Canberra.

Drug Utilisation Sub-Committee 2005, *Australian statistics on medicines 2003*, Department of Health and Ageing, Australian Government, Canberra.

Drugs and Crime Prevention Committee 2002, *Inquiry into the inhalation of volatile substances – Final report*, Drugs and Crime Prevention Committee, Parliament of Victoria, September.

Drugs and Crime Prevention Committee 2003, *Inquiry into amphetamine and 'party drug' use in Victoria – Discussion paper,* Drugs and Crime Prevention Committee, Parliament of Victoria.

Drugs and Crime Prevention Committee 2004, *Inquiry into amphetamine and 'party drug' use in Victoria – Final report*, Drugs and Crime Prevention Committee, Parliament of Victoria.

Drugs and Crime Prevention Committee 2006, *Inquiry into strategies to reduce harmful alcohol consumption – Final report*, Drugs and Crime Prevention Committee, Parliament of Victoria.

Drummer, OH 1994, *Drugs in drivers killed in Australian road accidents: The use of responsibility analysis to investigate the contribution of drugs to fatal accidents, report no. 594*, Victorian Institute of Forensic Pathology, Melbourne.

Drummer, O & Ranson, D 1996, 'Sudden death and benzodiazepines', *American Journal of Forensic Medicine and Pathology*, vol. 17, no. 4, pp.336–342.

Drummer, OH, Gerostamoulos, J & Batziris, H 1998, *Involvement of drugs in accident causation*, National Road Safety Summit, Federal Office of Road Safety, Canberra.

Duckett, SJ 2004, 'Drug policy down under: Australia's pharmaceutical benefits scheme', *Health Care Financing Review*, vol. 25, no 3, pp.55–67.

English, DR, Holman, CD, Milne, E, Winter, MH, Hulse, GK, Codde, G, Bower, CI, Cortu, B, de Klerk, N, Lewin, GF, Knuiman, M, Kurinczuk, JJ & Ryan GA 1995, *The quantification of drug caused morbidity and mortality in Australia*, Commonwealth Department of Human Services and Health, Canberra.

Erowid, Website. (Accessed at: http://www.erowid.org/general/about/about.shtml).

European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2005, *Annual report 2005 The state of the drugs problem in Europe, selected issue 3: Buprenorphine - treatment, misuse and prescription practices,* EMCDDA Lisbon, Portugal.

Faunce, T, Doran, E, Henry, D, Drahos, P, Searles, A, Pekarsky, B & Neville, W 2005, 'Assessing the impact of the Australia–United States Free Trade Agreement on Australian and global medicines policy', *Globalization and Health*, vol. 1, no 15 (Accessed at http://www.globalizationandhealth.com/content/1/1/15).

Feeney, GFX & Gibbs, H 2002, 'Digit loss following misuse of temazepam', *Medical Journal of Australia*, vol. 176, p.380.

Fishman, SM, 2004, Papazian, JS, Gonzalez, BS, Riches, PS & Gilson, A 2004, 'Regulating opioid through prescription monitoring programs: Balancing drug diversion and treatment of pain', *Pain Medicine*, vol 5, no. 3, pp.309–324.

Forgione, D, Neuenschwander, P & Vermeer, T 2001, 'Diversion of prescription drugs to the black market: What the States are doing to curb the tide', *Journal of Health Care Finance*, vol. 27, no. 4, pp.65–78.

Forman, RF, Woody, GE, McLellan, T & Lynch, KG 2006, The availability of web sites offering to sell opioid medications without prescriptions', *American Journal of Psychiatry*, vol. 163, no. 7, pp.1223–1238.

Fountain, J, Griffiths, P, Farrell, M, Gossop, M & Strang, J 1998, 'Diversion tactics: How a sample of drug misusers in treatment obtained surplus drugs to sell on the illicit market', *International Journal of Drug Policy,* vol. 9, pp.159–167.

Fountain, J, Strang, J, Gossop, M, Farrell, M & Griffiths, P 2000, 'Diversion of prescribed drugs by drug users in treatment: Analysis of the UK market and new data from London', *Addiction*, vol. 95, no. 3, pp.393–406.

Friedman, RA 2006, **'**The changing face of teenage drug abuse — The trend toward prescription drugs', *New England Journal of Medicine,* vol. 35, no. 14, pp.1448–1450.

Galbally, R 2000a, *National competition review of Drugs, Poisons and Controlled Substances legislation*, Final Report Part A, Commonwealth of Australia, Canberra.

Galbally, R 2000b, *National competition review of Drugs, Poisons and Controlled Substances legislation*, Final Report Part B, Commonwealth of Australia, Canberra.

Gijsbers, AJ & Whelan, G 2004, 'E-drug deals: Part of the wild west world of e-commerce', *Medical Journal of Australia*, vol. 180, pp.118–119.

Godfrey, D & Phillips, M 2003, 'Driving under the influence of drugs', *Policing Issues and Practice Journal*, January, pp.16–27.

Gordon, SM, Forman, RF & Siatkowski, C 2006, 'Knowledge and use of the internet as a source of controlled substances', *Journal of Substance Abuse Treatment,* vol. 30, no. 3, pp.271–274.

Gossop, M, Griffiths, P, Powis, B & Strang, J 1992, 'Severity of dependence and route of administration of heroin, cocaine and amphetamines', *British Journal of Addiction*, vol. 87, pp.1527–1536.

Gossop, M, Sewart, D, Treacy, S & Marsden, J 2002, 'A prospective study of mortality among drug misusers during a 4-year period after seeking treatment', *Addiction*, vol. 97, no. 1, pp.39–47.

Griffin, JP & O'Grady, J (eds) 2006, *The textbook of pharmaceutical medicine*, 5th edn, Blackwell Publishing, Oxford and Malden Massachusetts.

Griffin, JP & Shah, RR 2006, 'History of drug regulation in the United Kingdom, in JP Griffin & J O'Grady (eds), *The textbook of pharmaceutical medicine*, 5th edn, Blackwell Publishing, Oxford and Malden Massachusetts, pp.457–488.

Griffiths, RR, McLeod, DR, Bigalow, GE, Liebson, IA, Roache, JD & Nowowieski, P 1984, 'Comparison of diazepam and oxazepam: preference, liking and extent of abuse', *Journal of Pharmacology and Experimental Therapeutics*, vol. 229, pp.501–508.

Grimley Evans, J 1995, 'Evidence-based and evidence-biased medicine', *Age and Ageing*, vol. 24, pp.461–463.

Grudzinskas, C, Balster, RL, Gorodetzky, CW, Griffiths, RR, Henningfield, JE, Johanson, C, Mansbach, RS, McCormick, CG, Schnoll, SH, Strain, EC & Wright, C 2006, 'Impact of formulation on the abuse liability, safety and regulation of medications: The expert panel report', *Drug and Alcohol Dependence*, vol. 83, Supplement 1, June, pp.77–82.

Haydon, E, Rehm, J, Fischer, B, Monga, N & Adlaf, E 2005, 'Prescription drug abuse in Canada and the diversion of prescription drugs into the illicit drug market', *Canadian Journal of Public Health*, vol. 96, no. 6, pp.459–461.

Health Communication Network 2003, *MIMSOline*. (Accessed at: http://mims.hcn.net.au).

Health Insurance Commission (HIC), *Bulletin board*, April 2002. (Accessed at: http://www.medicareaustralia.gov.au/resources/pbs/bulletin_board/hic_pbs_bulletin_board_2002_04.pdf).

Health Insurance Commission (HIC), website, updated 22 September 2004. (Accessed July 2006 at: http://www.health.gov.au/internet/wcms/publishing.nsf/content/nmp-temazepam.htm).

Health report, Drug regulation and drug safety 2006, radio programme, ABC Radio National, 12 June (Accessed at: www.abc.net.au/rn/healthreport/stories/2006/1657545.htm).

Henry-Edwards, S, Gowing, L, White, L, Ali, R, Bell, J, Brough, R, Lintzeris, N, Ritter, A & Quigley, A 2003, *Clinical guidelines and procedures for the use of methadone in the maintenance treatment of opioid dependence*, Australian Government Department of Health and Ageing, Canberra.

Hirshorn, J & Monk, D 2006, 'The regulation of therapeutic products in Australia', in JP Griffin & J O'Grady (eds), *The textbook of pharmaceutical medicine*, 5th edn, Blackwell Publishing, Oxford and Malden Massachusetts, pp.652–684.

Hollinger, RC & Dabney, DA 2002, 'Social factors associated with pharmacists' unauthorized use of mind-altering prescription medications', *Journal of Drug Issues*, vol. 32, no. 1, pp.231–264.

Hulse, G, White, J & Cape, G (eds) 2002, *Management of alcohol and drug problems*, Oxford University Press, Melbourne.

Inciardi, JA, Surratt, HL, Kurtz, SP & Burke, JJ 2006, 'The diversion of prescription drugs by health care workers in Cincinnati, Ohio', *Substance Use and Misuse*, vol. 41, pp.255–264.

Industry Commission 1996a, *The pharmaceutical industry: The report*, vol 1, Report No 51, 3 May, AGPS, Melbourne.

Industry Commission 1996b, *The pharmaceutical industry: The appendices*, vol. 2, Report no 51, 3 May, AGPS, Melbourne.

International Harm Reduction Association (IHRA), *What is harm reduction?*, International Harm Reduction Association website. (Accessed at: http://www.ihra.net/popups/articleswindow).

Jaffe, J 1990, 'Drug addiction and abuse', in A Goodman, T Gilman, T Rall, A Nies & P. Taylor (eds.), *Goodman and Gilman's The pharmacological basis of therapeutics*, Pergamon, New York, pp.522–573.

Jarvis, TJ, Tebbutt, J, Mattick, R & Shand, F 2005, *Treatment approaches for alcohol and drug dependence: An introductory guide*, John Wiley and Sons Ltd, Chichester.

Jenkinson, R, Miller, P & Fry, C 2004, *Victorian drug trends 2003: Findings from the Illicit Drug Reporting System (IDRS)*, Technical Report no. 175, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney. (Accessed at: http://notes.med.unsw.edu.au/NDARCWeb.nsf/resources/TR_32/$file/TR.175.pdf).

Jenkinson, R, Clark, NC, Fry, CL & Dobbin, M 2005, 'Buprenorphine diversion and injection in Melbourne, Australia: An emerging issue?', *Addiction*, vol. 100, pp.197–205.

Jenkinson, R & O'Keeffe, B 2005, *Victorian drug trends 2004: Findings from the Illicit Drug Reporting System (IDRS)*, Technical Report no. 212, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney. (Accessed at: http://notes.med.unsw.edu.au/NDARCWeb.nsf/resources/TR_32/$file/TR.212.pdf).

Jenkinson, R & O'Keeffe, B. 2006, *Victorian drug trends 2005: Findings from the Illicit Drug Reporting System (IDRS)*, Technical Report no. 256, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney. (Accessed at: http://notes.med.unsw.edu.au/NDARCWeb.nsf/resources/TR_32/$file/TR.256.pdf).

Johnston, J & Jenkinson, R 2006, *Victorian drug trends in ecstasy and related drug markets 2005: Findings from the Party Drugs Initiative (PDI)*, Technical Report no. 246, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney. (Accessed at: http://notes.med.unsw.edu.au/NDARCWeb.nsf/resources/TR_32/$file/TR.246.pdf).

Johnston, LD, O'Malley, PM, Bachman, JG & Schulenberg, JE 2006, *Monitoring the future – national results on adolescent drug use: Overview of key findings, 2005*, NIH Publication no. 06-5882, National Institute on Drug Abuse, Bethesda, MD.

Join Together 2006, 'News summary: Column cast doubt on "pharming party" reports, 23 June'. (. Accessed 21 July 2006 at: http://www.jointogether.org/news/headlines/inthenews/2006/column-cast-doubt-on.html).

Jones, IF, 2000, 'Arsenic and the Bradford poisonings of 1858', *The Pharmaceutical Journal*, vol. 265, no. 7128, December 23/30, pp.938–939.

Katz, DA & Hays, LR 2004, 'Adolescent OxyContin abuse', *Journal of the American Academy of Child and Adolescent Psychiatry*, vol. 43, no. 2, pp.231–234.

Kelly, E, Darke, S & Ross, J 2004, 'A review of drug use and driving: Epidemiology, impairment, risk factors and risk perceptions', *Drug and Alcohol Review*, vol. 23, pp.319–344.

Koski, K, Luukinen, H, Laippala, P & Kivela, A 1996, 'Physiological factors and medications as predictors of injurious falls by elderly people: A prospective population-based study', *Age and Ageing*, vol. 26, pp.29–38.

Law, FD, Myles, JS, Daglish, MRC & Nutt, DJ 2004, 'The clinical use of buprenorphine in opiate addiction: evidence and practice', *Acta Neuropsychiatrica*, vol. 16, pp.246–724.

Lenne, MG, Dietze, P, Rumbold, G, Redman, JR & Triggs, TJ 2000, 'Opioid dependence and driving ability: A review in the context of proposed legislative change in Victoria', *Drug and Alcohol Review*, vol. 19, pp.427–439.

Lenton, S & Single, E 1998, 'The definition of harm reduction', *Drug and Alcohol Review*, vol. 17, no. 2, pp.213–220.

Lewis, P & Gaule, D 1999, 'Dealing with drug-seeking patients: The Tripler Army Medical Centre experience', *Military Medicine*, vol. 164, pp.838–840.

Lloyd, A, Guibert, R & Bell, J 2000, *Forged prescriptions study*, Pharmaceutical Society of Australia, Victorian Branch, Balwyn, Victoria.

Longo, L & Johnson, B 2000, 'Addiction: Part 1. Benzodiazepines – side effects, abuse risk and alternatives', *American Family Physician*, vol. 61, no. 7, pp.2121–2128.

Loo, H, Yam, A, Tan, T, Peng, Y & Teoh, L 2005, 'Severe upper limb complications from parenteral abuse of Subutex®', *Annals*, Academy of Medicine, Singapore, vol. 34, pp.575–578.

Loxley, W, Toumbourou, JW & Stockwell, T 2004, *The prevention of substance use, risk and harm in Australia: A review of the evidence*, Summary, Australian Government Department of Health and Ageing, Canberra.

Loxley, W, Toumbourou, JW, Stockwell, T, Haines, B, Scott, K, Godfrey, C, Waters, E, Patton, G, Fordham, R, Gray, D, Marshall, J, Ryder, D, Saggers, S, Sanci, L & Williams, J 2004, *The prevention of substance use, risk and harm in Australia: A review of the evidence*, National Drug Research Institute and the Centre for Adolescent Health, Commonwealth of Australia, Canberra.

McCabe, SE & Boyd, CJ 2005, 'Sources of prescription drugs for illicit use', *Addictive Behaviors,* vol. 30, no. 7, pp.1342–1350.

McCormick, C 2006, 'Regulatory challenges for new formulations of controlled substances in today's environment', Supplement, *Drug and Alcohol Dependence,* vol. 83, June, pp.63–67.

MacDonald, M & Zhou, J 2002, *Australian NSP survey national data report 1995–2001*, National Centre for HIV Epidemiology and Clinical Research, Sydney.

McGregor, C, Darke, S, Ali, R & Christie, P 1998, 'Experience of non-fatal overdose among heroin users in Adelaide, Australia: Circumstances and risk perceptions', *Addiction*, vol. 93, pp.701–711.

McNabb, C, Foot, C, Ting, J, Breeze, K & Stickley, M 2006, 'Profiling patients suspected of drug seeking in an adult emergency department', *Emergency Medicine Australia*, vol. 18, pp.131–137.

Martyres, RF, Clode, D & Burns, JM 2004, 'Seeking drugs or seeking help? Escalating "doctor shopping" by young heroin users before fatal overdose, *Medical Journal of Australia*, no. 180, pp.211–214.

Mazza, D & Russell, SJ 2001, 'Are GPs using clinical practice guidelines?', *Australian Family Physician*, vol 30, no 8, pp.817-820.

Measham, F, Aldridge, J & Parker, H 2001, *Dancing on drugs: Risk, health and hedonism in the British club scene*, Free Association Books, London.

Medical Practitioners Board of Victoria, website. (Accessed 6 July 2006 at: http://www.health.gov.au/internet/otd/publishing.nsf/content/work-medicalboards).

Medicare Australia 2005, *Professional services review scheme: Program Review and integrity*, Australian Government, Canberra. (Accessed at: http://www.medicareaustralia.gov.au/providers/program_review_integrity/psr.htm).

Miller, G 2005, 'Pharmacy: A look back at the past and a vision for the future: A scandalously short introduction to the history of pharmacy'. (Accessed at Pharmaceutical Society of Australia website: http://www.psa.org.au/ecms.cfm?id=91).

MIMS Online 2003, MIMS Online website. (Accessed at: Accessed at: http://MIMSOnline.hcn.net.au.dbgw.lis.curtin.edu.au/ifmx-nsapi/MIMSOnline-data.)

Ministry of Health, British Columbia, Canada, Government website. (Accessed 17 May 2006 at: http://www2news.gov.bc.ca/news_releases_2005).

Moore, D 2002, 'Ethnography and the Australian drug field: Emaciation, appropriation and multidisciplinary myopia', *International Journal of Drug Policy*, no. 13, pp.271–284.

National Center on Addiction and Substance Abuse (CASA) 2005, *Under the counter: The diversion and abuse of controlled prescription drugs in the U.S.*, CASA, Columbia University, New York.

National Centre for Epidemiology and Population Health, Australian National University, National Centre for Epidemiology and Population Health website. (Accessed at: http://nceph.anu.edu.au/Publications/Opioids/stage1vol2b.pdf).

National Centre for HIV Epidemiology and Clinical Research (NSHECR) 2005, *Australian NSP Survey: Prevalence of HIV and hepatitis C virus and injecting and sexual behaviour among IDUs at needle and syringe programs: National data report*, NSHECR, University of New South Wales, Sydney.

National Health Service Centre for Reviews and Dissemination 1999, *Effective health care: Getting evidence into practice*, Royal Society of Medicine Press, University of York, York, vol. 8, pp.63–74.

National Institute on Drug Abuse 2000, *Principles of drug addition treatment: A research based guide*, National Institutes of Health, Bethesda, Maryland.

O'Brien, CP 2001, 'Drug addiction and drug abuse', in JG Hardman, LE Limbird & A Goodman-Gilman (eds.), *The pharmacological basis of therapeutics*, 10th edn, McGraw-Hill, New York, pp.621–42.

Oliver, RG & Hetzel, BS 1972, 'Rise and fall of suicide rates in Australia: Relation to sedative availability', *Medical Journal of Australia*, vol. 2, pp.919–923.

Pharmacy Board of Victoria 2003, *Circular*, no. 52, October.

Pharmacy Board of Victoria 2004, *Guidelines for good pharmaceutical practice*, Parkfield, Victoria.

Pharmacy Society of Australia (PSA) 2006, 'DR-7 2000', Pharmacy self-help program, PSA website. (Accessed at: http://www.psa.org.au/ecms.cfm?id=238).

Porter, R (ed.) 2006, *The Cambridge history of medicine*, Cambridge University Press, Cambridge UK.

Pradel, V, Thirion, X, Ronfle, E, Masut, A & Micallef, J 2004, 'Assessment of doctor-shopping for high dosage buprenorphine maintenance treatment in a French region: Development of a new method for prescription data base', *Pharmacoepidemiology and Drug Safety*, vol. 13, pp.473–481.

Premier's Drug Prevention Council 2005, *Victorian youth alcohol and drug survey 2004 – Illicit drugs findings*, Premier's Drug Prevention Council, Victorian Government Department of Human Services, Melbourne.

Quigley, PA 2001, 'Public health dimensions of benzodiazepine regulation', *Critical Public Health*, vol. 11, no. 4, pp.331–339.

Rall, T 1992, 'Hypnotics and sedatives', in A Goodman, T Gilman. T Rall, A Nies & P. Taylor (eds), *Goodman and Gilman's The pharmacological basis of therapeutics*, vol. 1, McGraw-Hill, New York, pp.345–382.

Rang, HP, Dale, M & Ritter, J 2003, *Pharmacology*, 5th edn, Churchill Livingstone, Sydney.

Raspiller, MF, Bolyz, P, Pichot, N, Naoun, O & Lambert, H 2005, 'Non-infectious retinal artery complications in intravenous drug users', *Journal of Toxicology: Clinical Toxicology,* vol. 43, no. 5, pp.522–523.

Ray, WA, Thapa, PB & Gideon, P 2000, 'Benzodiazepines and the risk of falls in nursing home residents', *Journal of the American Geriatric Society*, June, vol. 48, no. 6, pp.682–685.

Rehm, J, Babor, TF & Room, R 2006, 'Education, persuasion and the reduction of alcohol-related harm: A reply to Craplet (2006)', *Addiction*, vol. 101, pp.452–453.

Reynaud, M, Petit, G, Potard, D & Courty, P 1998, 'Six deaths linked to concomitant use of Buprenorphine and benzosdiazepines', *Addiction*, vol. 93, no. 9, pp.1385–1392.

Richards, C 2005, 'When counting sheep does not help: the growing incidence of sleep disorders', *Drug Discovery Today,* vol. 10, no. 9, pp.611–614.

Robinson, GM, Kemp, R, Lee, C, & Cranston, D 2000, 'Patients in methadone maintenance treatment who inject methadone syrup: A preliminary study', *Drug and Alcohol Review,* vol. 19, pp.447–450.

Roche, AM 1998, 'Alcohol and drug education and training: A review of the key issues', *Drugs Education Prevention and Policy*, vol. 5, pp.85–99.

Ross, J, Darke, S & Hall, W 1996, 'Benzodiazepine use among heroin users in Sydney: Patterns of use, availability and procurement', *Drug and Alcohol Review*, vol. 15, pp.237–243.

Ross, J, Darke, S & Hall, W 1997, 'Transitions between routes of benzodiazepine administration among heroin users in Sydney', *Addiction*, vol. 92, no. 6, pp.697–706.

Ross, J & Darke, S 2000, 'The nature of benzodiazepine dependence among heroin users in Sydney, Australia', *Addiction*, vol. 95, no. 12, pp.1785–1793.

Royal Australian College of General Practitioners (RACGP), RACGP website. (Accessed 10 April 2001 at: http://www.racgp.org.au/policy/guidelines/benzo.htm)

Saunders, J & Young, R 2002, 'Medical and psychosocial problems', in G Hulse, J White & G Cape (eds), *Management of alcohol and drug problems*, Oxford University Press, Melbourne, pp.32–44.

Schulte, C, Mouzos, J & Makkai, T 2005, *Drug use monitoring in Australia: 2004 annual report on drug use among police detainees*, Australian Institute of Criminology, Canberra.

Schuster, C 2006, 'History and current perspectives on the use of drug formulations to decrease the abuse of prescription drugs', *Drug and Alcohol Dependence*, vol. 83, Supplement 1, June, pp.8–14.

Shakib, S & George, A 2003, 'Prescribing: What's all the fuss?', *Australian Family Physician*, vol 32, no 1 / 2, January/February, pp.35–38.

Shand, F, Gates, J, Fawcett, J & Mattick, R 2003, *Guidelines for the treatment of alcohol problems*, Commonwealth of Australia, Canberra.

Shaw, S, Cartwright, A, Spratley, T & Harwin, J 1978, *Responding to drinking problems*, Croom Helm, London.

Siegal, H, Carlson, R, Kenne, D & Swora, M 2003, 'Probable relationship between opioid abuse and heroin use', *American Family Physician*, vol. 67, no. 5, pp.942–94.

Stafford, J, Degenhardt, L, Black, E, Bruno, R, Buckingham, K, Fetherston, J, Jenkinson, R, Kinner, S, Moon, C & Weekley, J 2005, *Australian drug trends 2004: Findings from the Illicit Drug Reporting System (IDRS)*, Monograph no. 55, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney.

Stafford, J, Degenhardt, L, Black, E, Bruno, R, Buckingham, K, Fetherston, J, Jenkinson, R, Kinner, S, Newman, J & Weekley, J 2006, *Australian drug trends 2005: Findings from the Illicit Drug Reporting System (IDRS)*, Monograph no. 59, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney.

Stafford, J, Degenhardt, L, Dunn, M, Fischer, J, George, J, Johnston, J, Matthews, A, Newman, J, Proudfoot, P & Weekley, J 2006, *Australian trends in ecstasy and related drug markets 2005: Findings from the Party Drugs Initiative (PDI)*, Monograph no. 58, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney.

St George, BN, Emmanuel, JR & Middleton, KL 2004, 'Overseas-based online pharmacies – a source of supply for illicit drug users?', *Medical Journal of Australia*, vol. 180, pp.103–104.

Strang, J, Powis, B, Best, D, Vingoe, L, Griffiths, P, Taylor, C, Welch, S & Gossop, M 1999, 'Preventing opiate overdose fatalities with take-home naloxone: Pre-launch study of possible impact and acceptability', *Addiction*, vol. 94, no. 2, pp.199–204.

Substance Abuse and Mental Health Services Administration (SAMHSA) 2005, *Results from the 2004 National Survey on Drug Use and Health: National Findings*, Office of Applied Studies, NSDUH Series H-28, DHHS Publication no. SMA 05-4062, DHHS, Rockville, MD.

Sunjic, S & Howard, J 1996, '"Non-injectables": Methadone syrup and benzodiazepine injection by methadone-maintained clients', *Drug and Alcohol Review*, vol. 15, pp.245–50.

Swensen, G, Illett, KF, Dusci, LJ, Hackett, P, Ong, RTT, Quigley, AJ, Lenton, S, Saker, R & Caporn, J 1993, 'Patterns of drug use by participants in the Western Australian methadone program, 1984–1991', *Medical Journal of Australia*, vol. 159, pp.373–376.

Tamblyn, R, Abrahamowicz, M, du Berger, R, McLeaod, P & Bartlett, G 2005, 'A 5-year prospective assessment of the risk associated with individual benzodiazepines and doses in new elderly users', *Journal of the American Geriatrics Society*, vol. 53, pp.233–241.

Taylor, JL & Tinklenberg, JR 1987, 'Cognitive impairment and benzodiazepines', in HY Meltzer (ed.), *Psychopharmacology: The third generation of progress*, Raven Press, New York, pp.1449–1454.

Taylor, N, Prichard, J & Charlton, K 2004, *National project on drink spiking: Investigating the nature and extent of drink spiking in Australia*, Ministerial Council on Drug Strategy, Canberra.

Taylor, S & Chermack, S 1993, 'Alcohol, drugs and human physical aggression', *Journal of Studies of Alcohol*, vol. 11, pp.78–88.

Therapeutic Goods Administration (TGA) 2003, *History of the Australian Drug Evaluation Committee*, Paper published at TGA website August 2003 (no listed author). (Accessed at TGA website: www.tga.gov.au/docs/html/adec/adec_history.htm).

Therapeutic Goods Administration (TGA) 2005a, *Scheduling policy framework for medicines and poisons – consultation draft*, July, TGA, Canberra. (Accessed at TGA website: www.tga.gov.au/consult/2005/scheduling/htm).

Therapeutic Goods Administration (TGA) 2005b, *A proposed model for the scheduling of medicines – consultation document*, July, TGA Canberra. (Accessed at TGA website: www.tga.gov.au/consult/2005/scheduling/htm).

The Shipman Report 2005. (Accessed at: http://www.the-shipman-inquiry.org.uk).

Topp, L 2006, 'Pharmaceutical diversion: Accidental harm reduction?', *Of Substance*, vol. 4, no. 2, pp.6–9.

Topp, L, Darke, S, Bruno, R, Fry, C, Hargreaves, K, Humeniuk, R, McAllister, R, O'Reilly, B & Williams, P 2001, *Australian drug trends 2000: Findings from the Illicit Drug Reporting System (IDRS)*, Monograph no. 47, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney.

Topp, L, Kaye, S, Bruno, R, Longo, M, Williams, P, O'Reilly, B, Fry, C, Rose, G & Darke, S 2002, *Australian drug trends 2001: Findings from the Illicit Drug Reporting System (IDRS)*, Monograph no. 48, National Drug and Alcohol Research Centre (NDARC), University of New South Wales, Sydney.

Tough, 2001, 'The alchemy of OxyContin: From pain relief to drug addiction', *New York Times*, 21 July. (Accessed 20 July 2006 at: http://query.nytimes.com/gst/fullpage.html?sec=health&res=9403E2DF113AF93AA15754C0A9679C8B63).

Tunnell, KD 2005, 'The OxyContin epidemic and crime panic in rural Kentucky', *Contemporary Drug Problems*, vol. 32, no. 2, pp.225–258.

United Nations International Drug Control Program (UNDCP) 2000, *Demand reduction: A glossary of terms*, ODCCP Studies on Drugs and Crime, Vienna.

United Nations Office of Drugs and Crime (UNODC) 2006a, *2006 World drug report: Volume 1: Analysis*, UNODC, Geneva.

United Nations Office of Drugs and Crime (UNODC) 2006b, *2006 World drug report: Volume 2: Statistics*, UNODC, Geneva.

United States General Accounting Office 2003, *Prescription drugs: Factors that may have contributed to OxyContin abuse and diversion and efforts to address the problem (GAO Item No. GAO-04-110*, General Accounting Office, Washington DC.

Velleman, R, Bennett, G, Miller, T, Orford, J, Rigby, K & Tod, A 1993, 'The families of problem drug users: A study of 50 close relatives', *Addiction*, vol. 88, pp.1291–1289.

Victorian State Coroner's Office 2000, *Heroin-related overdose project*, Inquests into the deaths of David Borg, David Eberhardt, Sally Jessup, Clinton McLeod, Baskel Summut and Matthew Try, State Coroner's Office, Melbourne.

Ward, J, Mattick, R & Hall, W 1998, *Methadone maintenance treatment and other opioid replacement therapies*, Harwood Academic Publishers, Australia.

Ward, S, Heyenman, L, Reittner, P, Kazeroonic, E, Goodwin, J & Muller, N 2000, 'Talcosis associated with IV abuse of oral medications: CT findings', *American Journal of Roentgenolgy*, vol. 174, pp.789–793.

Weizman, T, Gelkopf, M, Melamed, Y, Adelson, M & Bleich, A 2003, 'Treatment of benzodiazepine dependence in methadone maintenance treatment patients: A comparison of two therapeutic modalities and the role of psychiatric comorbidity', Australian and *New Zealand Journal of Psychiatry*, vol. 37, no. 4, pp.458–463.

White, J & Taverner, D 1997, 'Drug seeking behaviour', *Australian Prescriber*, vol. 20, no. 20, pp.68–70.

Wikipedia – The online encyclopaedia (Accessed 20/07/06 at: http://en.wikipedia.org/wiki/Pharming_parties).

Wild, TC 2006, 'Social control and coercion in addiction treatment: Towards evidence-based policy and practice', *Addiction*, vol. 101, no. 1, pp.40–49.

Williams, H, Oyefeso, A & Ghodse, A 1996, 'Benzodiazepine misuse and dependence among opiate addicts in treatment', *Irish Journal of Psychological Medicine*, vol. 13, pp.62–64.

Winford, S 2006 'Drug offences' in K Harper (ed.), *The law handbook*, Fitzroy Legal Service, Fitzroy Victoria, pp.118–132.

Woods, J, Gerostamoulos, D, Drummer, OH & Cordner, S 2006, *Heroin deaths in Victoria, report no. 9*, Victorian Institute of Forensic Medicine & Department of Forensic Medicine, Monash University, Melbourne.

World Health Organization (WHO) 1994, *Lexicon of alcohol and drug terms*, WHO, Geneva.

World Health Organization (WHO) 1996, *The rational use of benzodiazepines*, Program on Substance Abuse, WHO, Geneva.

World Health Organization (WHO) 2002, *Effective drug regulation: A multi-country* study, Report prepared for the World Health Organization by Sauwakon Ratanawijitrasin and Eshetu Wondemagegnehu, WHO, Geneva.

Wrobel, JP 2003, 'Are we ready for the Better Medication Management System?', *Medical Journal of Australia*, vol. 178, no. 5, pp.448–450.

Young, R, Saunders, J, Hulse, G, McLean, S, Martin J, Robinson, G 2002, 'Opioids', in G Hulse, J White & G Cape (eds), *Management of alcohol and drug problems*, Oxford University Press, Melbourne, pp.79–99.

Zador, D 2000, 'Discussant paper', in Humeniuk, R, Ali, R, White, J, Hall, W & Farrell, M, *Proceedings of expert workshop in the induction and stabilisation onto methadone*, Monograph no. 39, Commonwealth Department of Health and Ageing, Adelaide, pp.33–43.

Zinberg, NE 1984, *Drug, set and setting: The basis for controlled intoxicant use*, Yale University Press, New Haven.