NCETA
Australia's National Research Centre on AOD Workforce Development

Flinders UNIVERSITY

A Matter of Balance

A background discussion paper to support the development of the National Pharmaceutical Drug Misuse Strategy (NPDMS)

March 2011

This discussion paper and its content are intended to inform the consultation processes that will be undertaken during the developmental phase of the NPDMS.

Further information about the NPDMS can be obtained from NCETA
Ph 08 8201 7535 or www.nceta.flinders.edu.au

Foreword

A National Pharmaceutical Drug Misuse Strategy (NPDMS) is being developed at the request of the Ministerial Council on Drug Strategy (MCDS) and is funded through the MCDS Cost Shared Funding Model. The strategy development is being undertaken by a consortium led by the National Centre for Education and Training on Addiction (NCETA) at Flinders University. The project is being overseen by the Victorian Department of Health.

This discussion paper provides a brief overview of issues relevant to the development of Australia's NPDMS. For a more comprehensive coverage of these issues, readers are invited to examine the full literature review available at www.nceta.flinders.edu.au. The discussion paper outlines the background and context for the initiation of a pharmaceutical misuse strategy, relevant Australian and international research and data, and potential areas for prevention and remediation that may be addressed through the strategy. It was informed by the literature review and discussions with key experts in the area from a variety of backgrounds. This paper is not intended to be a definitive coverage of issues; rather, it is intended to be thought provoking, stimulating and in some respects challenging.

The document will be used as the basis to inform and guide the national consultation process. The consultation process will provide an opportunity to address whether the discussion paper and the associated literature review:

- *contain significant gaps (for example, issues, research, information, resources and examples of good practice);*
- *accurately reflect the state of play;*
- *reflect stakeholders' interests and concerns; and*
- *contain potential responses that are consistent with stakeholders' perspectives.*

Throughout this paper key questions are posed which are intended to stimulate discussion in relation to the extent and nature of pharmaceutical drug misuse and potential responses. These questions appear in red.

The time frame for consultation for the development of the Strategy is as follows:

- *discussion paper released March 2011;*
- *a national consultation process will occur between late March and early June; and*
- *written submissions will be called for mid-March to the end of May.*

Written submissions to the development process are welcome. Information about submissions is available at www.nceta.flinders.edu.au or by phoning 08 8201 7535.

The closing date for written submissions will be 27 May 2011.

In developing the NPDMS a range of potential clinical responses to problems such as chronic non-malignant pain, anxiety and insomnia will be examined. In assessing the quality of evidence that supports these, the Australian National Health and Medical Research Council's evidence assessment framework will be relied upon. This involves various levels of evidence[1]. Responses to complex social problems, such as pharmaceutical drug misuse,

[1] Level 1 consists of evidence obtained from a systematic review of all relevant randomised controlled trials.
Level 2 consists of evidence obtained from at least one properly-designed randomised controlled trial.
Level 3-1 consists of evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
Level 3-2 consists of evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
Level 3-3 consists of evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.
Level 4 consists of evidence obtained from case series, either post-test or pre-test/post-test (National Health and Medical Research Council, 2000).

cannot always be fully informed by high-level evidence. Potential responses to this problem (such as prescription monitoring programs or coordinated medication management systems, for example), do not lend themselves to evaluation by randomised controlled trials.

Therefore, where possible, the measures ultimately proposed in the NPDMS will be based on high-level evidence, but on the understanding that with complex issues such as this, high-level evidence is not always available.

Table of Contents

List of Tables

List of Figures

List of Questions

Abbreviations

AIHW	Australian Institute of Health and Welfare
ADF	Abuse deterrent formulations
AHPRA	Australian Health Practitioner Regulation Agency
ARF	Abuse resistant formulations
BPS	British Pain Society
CASA	Center for Addiction and Substance Abuse
CDS	Centers for Disease Control and Prevention
CMMS	Coordinated Medication Management System
CNMP	Chronic Non-Malignant Pain
CNS	Central Nervous System
DCPC	Drugs and Crime Prevention Committee of the Parliament of Victoria
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
GP	General Practitioner
INCB	International Narcotics Control Board
MCDS	Ministerial Council on Drug Strategy
MSIC	Medically Supervised Injection Centre
NE-HS	National E-Health Strategy
NCETA	National Centre for Education and Training on Addiction
NCHECR	National Centre in HIV Epidemiology and Clinical Research
NDS	National Drug Strategy
NMHS	National Mental Health Strategy
NPDMS	National Pharmaceutical Drug Misuse Strategy
NPS	National Prescribing Service Ltd
NSP	Needle and Syringe Program
NSQUM	National Strategy for the Quality Use of Medicines
OST	Opioid Substitution Therapy
OTC	Over the counter
PBS	Pharmaceutical Benefits Scheme
PMP	Prescription Monitoring Program
QUM	Quality Use of Medicines
RACP	Royal Australasian College of Physicians
RFID	Radio frequency identification
RUM	Return Unwanted Medicines
SAMHSA	Substance Abuse and Mental Health Service Administration
SNRI	Serotonin-noradrenaline (norepinephrine) reuptake inhibitors
SSRI	Selective serotonin reuptake inhibitors
UNODC	United Nations Office on Drugs and Crime

Glossary of Medicines

Alprazolam	A benzodiazepine used to treat anxiety, anxiety associated with depression, panic attacks and phobias
Barbiturate	Potent central nervous system depressant
Benzodiazepines	A group of drugs used to treat anxiety, insomnia, muscle spasm and spasticity, seizures, and alcohol withdrawal
Buprenorphine	Partial opioid agonist used to treat moderate to severe pain
Diazepam	Benzodiazepine used to treat anxiety, acute alcohol withdrawal, muscle spasm and spasticity
Hydrocodone	Opioid analgesic used to treat moderate to severe pain and as a cough suppressant
Ibuprofen	Non steroidal anti-inflammatory drug
Methadone	Synthetic opioid analgesic used to treat opioid dependence and severe pain
Oxazepam	Benzodiazepine used to treat anxiety and anxiety associated with depression
Oxycodone	Opioid analgesic used to treat moderate to severe pain
Propoxyphene	Analgesic used to treat mild-moderate pain
Pseudoephedrine	Nasal decongestant used in the general treatment of cold/flu symptoms
Temazepam	Benzodiazepine used to treat insomnia
Tramadol	Centrally acting synthetic opioid-like analgesic used to treat moderate-severe pain
Zolpidem	Non-benzodiazepine used to treat insomnia
Zopiclone	Non-benzodiazepine used to treat insomnia

Glossary of Terms

- Adjuvant drugs are medications often used in the management of persistent pain, although their usual role is for conditions other than pain.
- Chronic non-malignant pain is pain that is non-cancerous in origin and that persists beyond normal tissue healing time, which is assumed to be approximately three months.
- Controlled drugs are medicines with a high potential for misuse which are on Schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons in Australia.
- Coordinated medication management systems/prescription monitoring programs are systems to record the prescription, dispensing and/or supply of defined medications to individuals, to be provided to prescribers and/or pharmacists at the time of prescribing, dispensing or supply, and can also be used for monitoring the supply of these medications by regulatory authorities.
- Drug dependence: the term implies a need for repeated doses of a drug to feel good or to avoid feeling bad. It also refers to a cluster of cognitive, behavioural and physiologic symptoms that indicate a person has impaired control of psychoactive substance use and continues use of the substance despite adverse consequences.
- Pharmaceutical drug misuse is the use of prescription or over-the-counter drugs by individuals, using routes of administration or at dosages that were unintended by the prescriber or pharmacist at the time of prescribing, dispensing or supply, or use to deliberately obtain an intoxicating effect.
- Iatrogenic dependence is dependence stemming from medical treatment or advice.
- Inappropriate prescribing is the prescribing of medications in a manner that is inconsistent with their quality use.
- Non-medical use of pharmaceutical drugs occurs in order to induce or enhance a drug-related experience, for non-clinically indicated performance enhancement or for cosmetic purposes.
- Opioids are chemicals that bind to opioid receptors in the body and result in effects such as analgesia, euphoria, sedation, respiratory depression and constipation. Opioids can be classified as natural, semi-synthetic, fully synthetic or endogenous.
- Pharmaceutical drugs are drugs available from pharmaceutical sources, (i.e. manufactured by the pharmaceutical industry or made up by a pharmacist) which are intended for use in the diagnosis, cure, treatment, or prevention of disease.
- Psychopharmacology is the study of drug-induced changes in mood, sensation, thinking, and behaviour.
- Unsanctioned use is use of a substance that is not approved by a society or by a group within society.

1 Why a Strategy?

Pharmaceutical drug misuse is an emerging issue of significant concern. This trend involves a wide range of pharmaceutical drugs, not least of which is the opioids. Trends of rapidly increasing supply of prescription opioids in the United States, for example, have been accompanied by increasing misuse and an escalating number of deaths involving opioid analgesics, described as a 'drug death epidemic'. While overseas trends may not always be replicated here, it is noteworthy that Australia has also experienced a substantial increase in the supply of prescription opioids in recent years and is now starting to see a range of harms emanating from this (see sections 7 & 9). These include:

- increased numbers of pharmaceutical drug-related emergency department presentations and fatal and non-fatal overdoses;
- harms associated with the injection and inhalation of pharmaceuticals intended to be taken orally;
- increased numbers of individuals seeking treatment for prescription opioid or benzodiazepine dependence;
- increased levels of trafficking in pharmaceutical drugs; and
- increased hospital treatment of prescription opioid poisoning which now substantially exceeds that for heroin poisoning.

A critical factor in the development of the NPDMS will be ensuring that a balance is achieved between diverse perspectives and interests. There is also a need to ensure continued medical access to these medications and maximising their appropriate use, while minimising opportunities for misuse. These medications are highly beneficial to many individuals and there is a need to ensure that the clinically appropriate supply of these medications is maintained and use is in no way stigmatised.

There is also a need to have measures in place to minimise the harm from any unsanctioned use of these medications. This includes use by those other than for whom the drugs were prescribed, or at doses, or via routes of administration, that were unintended by the prescriber.

2 The Scope of the Strategy

The Strategy will have potential relevance to a wide variety of prescription and over the counter (OTC) pharmaceutical drugs which are subject to non-medical use, misuse and/or diversion. The prescription drugs of relevance include opioids, benzodiazepines, psycho-stimulants, anti-depressants, anti-psychotics and performance and image enhancing drugs. The OTC drugs of relevance include codeine-containing analgesics, pseudoephedrine and anti-histamines.
Currently in Australia the medications associated with the greatest levels of harm are the pharmaceutical opioids, benzodiazepines and over the counter (OTC) codeine-containing analgesics. Consequently, at the request of the MCDS, the NPDMS will focus on these drugs. The strategy will also use these drugs as strategy development 'prototypes', because many of the responses developed to address actual and potential problems with these drugs will also have applicability to other drugs of concern. In addition, much work has already been undertaken to address problems with some of these other medications[2].

The NPDMS will be informed by Australia's approach to the quality use of medicines (QUM). Like Australia's National Strategy for the Quality Use of Medicines (NSQUM) the NPDMS will seek to improve the QUM by involving healthcare consumers, practitioners, providers and educators, the medicines industry and governments. Development of the NPDMS will involve the application of many aspects of the NSQUM, and the broader National Medicines Policy to the problems associated with opioids and similar drugs.

The strategy will focus on a number of key issues, including:
1. medication monitoring and regulatory processes and their interface with the clinical environment;
2. the healthcare workforce development needs required to enhance quality use of these medicines, especially the workforce development needs of prescribers and pharmacists;
3. where necessary, recommending the development and implementation of guidelines to enhance the QUM in relation to conditions such as chronic non-malignant pain, anxiety and insomnia;
4. examining what regulatory, monitoring and investigative resources might be required to effectively address medication shopping and the illicit supply of pharmaceuticals for profit, including consideration of timely and appropriate information exchange between health and police agencies;
5. national data availability concerning the extent and nature of misuse of these medications; and
6. the measures required to minimise the harm from unsanctioned use of these medications.

The strategy will also address a range of structural issues; including the complex array of ways in which pharmaceutical drug misuse problems interact with Australia's social environment, including its health and welfare systems and the structural determinants of the health of Australians. A range of other factors will be taken into consideration in the development of the NPDMS. These include: Australians' expectations of the potential benefits of medicines; the impact of the Internet; increasingly well informed and assertive patients; and the ageing of Australia's population.

[2] For example a considerable amount of work has been undertaken in Western Australia to address problems associated with the misuse of pharmaceutical amphetamine type stimulants.

3 Key Stakeholders

The NPDMS is of relevance to a wide range of stakeholders. These include:

- all Australian citizens;
- a range of prescribers including general practitioners and pain, addiction and psychiatric specialists;
- pharmacists;
- regulators of drugs and poisons;
- the pharmaceutical industry at a range of levels;
- government-funded bodies such as the National Prescribing Service Ltd and the Australian Commission on Safety and Quality in Health Care;
- members of the peak pharmaceutical advisory bodies such as the Pharmaceutical Benefits Advisory Committee, the National Medicines Policy Executive and the National Medicines Policy Committee;
- policing and other law enforcement agencies;
- drug treatment providers;
- other health and human service providers including psychologists, physiotherapists, nurses and counsellors;
- individuals suffering from chronic pain, mental health problems, social disadvantage and their respective advocacy groups; and
- current misusers of these drugs.

Figure 1 provides an indication of the diversity of groups involved as key stakeholders in the development of the NPDMS.

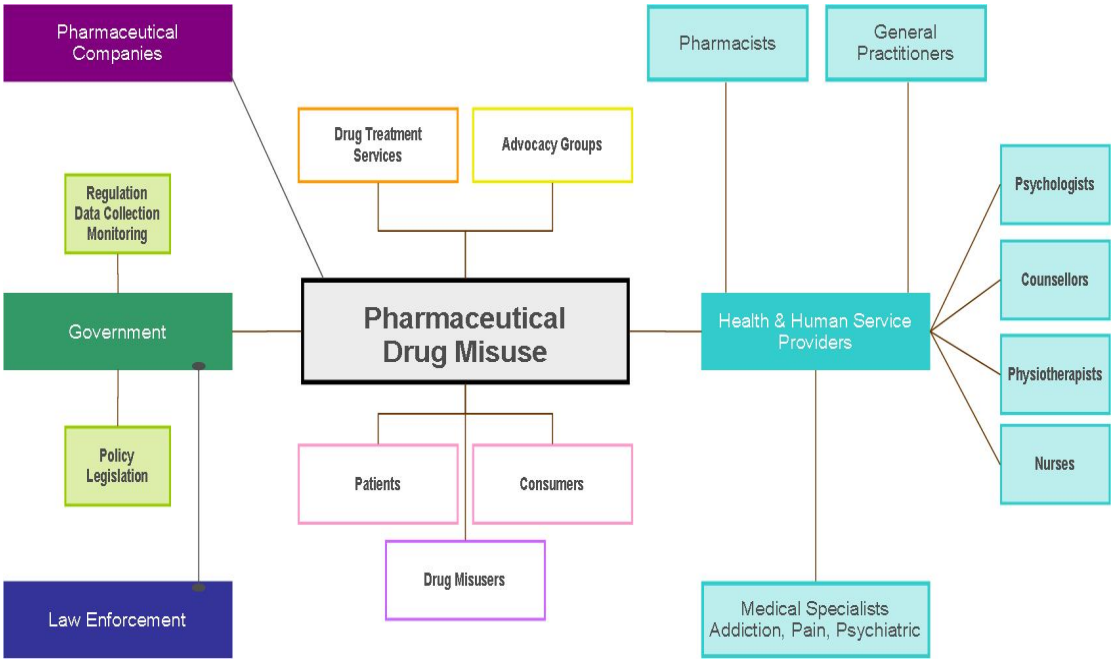

Figure 1. Key stakeholders with a role in the development of the NPDMS

The strategy will seek input from these groups and will endeavour to balance the diverse perspectives involved.

Question 1

Are there any other key stakeholders of relevance to the development of the NPDMS?

4 The Context for the Strategy

The NPDMS is being developed in the context of a diverse range of factors which need to be taken into consideration. These factors include the following:

4.1 Knowledge / information gaps

Currently it is not possible to accurately quantify or comprehensively respond to problematic pharmaceutical use, and prescription opioid use in particular, in Australia because:

1. existing monitoring systems cannot identify and track the medications themselves to the individual patient level;
2. many existing monitoring systems do not cover all prescription drugs, cannot track prescriptions to the individual patient and/or cannot do so in a timely manner;
3. the regulation of pharmaceutical opioids varies between jurisdictions, which impedes the implementation of strategies to deal with problematic opioid use, and facilitates individuals seeking these drugs across state/territory borders;
4. at times, discrete information is held by different agencies (such as health and law enforcement agencies) and across different jurisdictions, which is not necessarily merged to form a comprehensive picture;
5. although there is little evidence that international Internet pharmacies are currently a significant source of these medications, they have the potential to further weaken the regulatory controls over prescription opioids and other medications;
6. research into these matters in Australia has been very limited;
7. inadequate monitoring systems make fraudulent presentation for opioid prescriptions difficult to identify and respond to in health settings (e.g. general practice, community pharmacies and emergency departments) (RACP, 2009, p. 8);
8. data available from the Pharmaceutical Benefits Scheme does not include information on all medicines prescribed in Australia;
9. police do not have access to the data they require to effectively respond to that portion of the misuse of pharmaceuticals that involves the illicit sale of medications; and
10. problems are being caused by the national registration of health practitioners and the subsequent ability for Schedule 8 prescriptions written in one jurisdiction to be filled in another.

Question 2

Are there any other significant gaps in our knowledge?

4.2 The social determinants of health

Over the past decade, there has been an increased global focus on the importance of the social determinants of health (The Marmot Review, 2010). This entails the conditions in which people are born, grow, live, work and age, including the health system, and the influence of these factors on health quality. These influences are often shaped by the distribution of money, power and resources and access to

services. The social determinants of health are increasingly seen as major contributory factors in a range of health-related issues (Commission on the Social Determinants of Health, 2008). There is increasing recognition that factors such as socioeconomic status significantly influence health problems such as chronic pain, levels of mental illness and illicit drug use. Hence, the misuse of pharmaceuticals should not be seen exclusively as a medical problem but understood in its broader social context.

Question 3

How do factors impacting on the social determinants of health impact on the misuse of pharmaceuticals?

4.3 The National Drug Strategy (NDS)

The NDS seeks to minimise the harm associated with alcohol and other drug use by utilising a balanced approach aimed at supply, demand and harm reduction. This also forms a key framework from which to address the issue of pharmaceutical misuse. The Strategy is available at: http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/Content/consult.

4.4 The National Health Reform Agenda

The development of the NPDMS is occurring at the same time that the Australian Government has established a major health reform agenda to address the significant challenges facing the health system. These implications for the NPDMS include: the emphasis on prevention and early intervention; the reshaping of Medicare to better reflect the utility of non-pharmacological interventions by prescribers; better integration of health care services among multi-disciplinary providers; enhancement of the evidence bases which inform practice; and improved use of E-Health information and technology. More information about the reform agenda is available at:

1. http://www.health.gov.au/internet/nhhrc/publishing.nsf/Content/nhhrc-report
2. http://www.health.gov.au/internet/yourhealth/publishing.nsf/Content/report-primaryhealth
3. http://www.health.gov.au/internet/preventativehealth/publishing.nsf/Content/discussion-healthiest

4.5 The National E-Health Strategy (NE-HS)

The NE-HS seeks to use technology to enhance the functioning of Australia's Health Care System. The NE-HS will be critically important in relation to issues such as the potential implementation of Coordinated Medication Management Systems to enhance the quality use of medicines in Australia. The NE-HS is available at: http://www.ahmac.gov.au/site/home.aspx.

4.6 The National Pain Strategy (NPS)

Understanding and addressing pain is central to the NPDMS and the NPS helps to reconceptualise pain. It aims to improve quality of life for people with pain and their families and to minimise the burden of pain on individuals and the community. It seeks to: enhance the extent to which pain is regarded as a national priority; empower consumers; improve the use of evidence-based responses; and de-stigmatise the predicament of people with pain, especially chronic non-malignant pain (CNMP).

A central aim of the NPDMS will be to ensure that clinically appropriate access to pain medications is assured, while minimising opportunities for misuse. It will also be important to ensure that measures designed to minimise misuse of these medications do not inadvertently stigmatise their use. The NPS is available at: http://www.painsummit.org.au/strategy/.

4.7 The National Mental Health Strategy (NMHS)

The NMHS seeks to promote the mental health and well-being of the Australian community and, where possible, prevent the development of mental health problems and mental illness; reduce the impact of mental health problems and mental illness, including the effects of stigma on individuals, families and the community; promote recovery from mental health problems and mental illness; and assure the rights of people with mental health problems and mental illness, and to enable them to participate meaningfully in society.

The National Mental Health Strategy is available at: http://www.health.gov.au/internet/main/publishing.nsf/content/mental-strat

Question 4

How do these agendas and strategies impact on Australia's responses to pharmaceutical drug misuse?

4.8 The Pharmaceutical Benefits Scheme

The Australian Government aims to provide reliable, timely and affordable access to cost-effective, sustainable and high quality pharmaceutical services and medicines. Central to achieving this aim is the Pharmaceutical Benefits Scheme (PBS) which subsidises the cost of medicines. Continued access to these medicines, within the context of the QUM principles is important, as they are highly beneficial to many individuals.

There is no doubt that the PBS is an extremely valuable program. Nevertheless, a key issue is whether the improved drug affordability associated with the PBS leads to the preferential use of medications by prescribers rather than non-medical alternatives, regardless of their respective efficacy. The current structuring of benefits payable on the PBS may also encourage prescribers to prescribe certain drugs because they are cheaper, rather than because they are the most appropriate drug for patients' conditions.

Question 5

How do the current operations of the PBS contribute to, or reduce, the misuse of pharmaceutical drugs?

4.9 Other Australian Government Initiatives

The Australian Government also provides advice to health professionals and consumers on the quality use of medicines. This includes funding of the National Prescribing Service (NPS) to provide independent, evidence-based information on various drug and therapeutic topics. NPS information and resources supplement a range of other resources available to health professionals to improve prescribing and dispensing. These resources include information on medicines provided by pharmaceutical companies, guidelines such as those prepared by medical colleges and other sources such as Therapeutic Guidelines and the Australian Medicines Handbook.

Medicare Australia is responsible for administering the Australian Government's national health programs. Medicare Australia's compliance approach involves risk detection including identifying, assessing and prioritising risks to the integrity of the programs they administer. One of the primary risks to the PBS is the prescription of PBS medicines to patients who do not meet the requirements for these medicines. Prescribers have an important role in deciding who is eligible, in particular, for restricted and authority medicines.

Medicare Australia also researches and monitors prescribing. A major focus is on supporting prescribers to understand their obligations. Drugs of dependence are a particular area of concern and focus. In exceptional circumstances, the Practitioner Review Program may review specific prescribing concerns that may be considered as potentially inappropriate. Further review may lead Medicare Australia to refer a case to the Director of the Professional Services Review for peer review.

The Professional Services Review plays an important role in educating practitioners and deterring inappropriate practices. The *2008-09 Professional Services Review: Report to the Professions* (PSR, no date) found that inappropriate prescribing of controlled drugs and benzodiazepine drugs was a significant issue in a number of GP referrals. Patient demand for these drugs, as well as an over readiness by some practitioners to prescribe, is seen as a continuing problem.

4.10 The policing perspective

It is not just the health sector that is impacted by problematic pharmaceutical misuse. As Nicholas (2002) asserted, the diversion of pharmaceuticals represents a complex series of problems for policing, including:

- providing an additional dynamic to the already complex illicit drug markets;
- the behavioural problems associated with intoxication with pharmaceutical drugs;
- crime committed while under the influence of pharmaceutical drugs or in order to obtain them; and
- driving while under the influence of pharmaceutical drugs.

Fry et al. (2007) highlighted a range of other issues that pharmaceutical opioid and benzodiazepine markets pose for police. These include:

- the difficulties associated with distinguishing licitly and illicitly held prescription pharmaceuticals;
- the requirement for police to have knowledge of relevant scheduling and legislative considerations;
- the need for police to have an understanding of psychopharmacology of benzodiazepines and prescribed opioids, their interactions with illicit drugs, and the implications for behaviour; and
- the fact that similar policing responses are required regardless of whether intoxication is due to use of licit or illicit drugs.

Trafficking in illicit pharmaceutical drugs is a major emerging problem for police in some jurisdictions. The relative ease with which these drugs can be cheaply obtained and the potential profits to be made from their illicit sale is encouraging entrepreneurs to enter the illicit pharmaceuticals market. This ranges from, for example, patients who 'use a bit and sell a bit', through to those who are making considerable profits from the enterprise. This trend is becoming particularly prevalent in some rural areas, but is also evident in urban settings. Police are increasingly encountering individuals travelling from town to town, sometimes across several jurisdictions to obtain substantial quantities of opioids and other pharmaceuticals from a variety of doctors and pharmacies. These drugs are then being on-sold in the community.

This is very problematic from a policing perspective because the information that police require to respond to these problems is held by the health sector and, at times, by different state/territory and national jurisdictions. This means that the data is not easily accessible to police and nor is it accessible in a timely manner. As a result, it is only possible for police to access relevant information when a problem with illicit supply is already causing significant levels of harm in the community. This is a major barrier to the investigation of these crimes.

A further difficulty is that crimes related to the diversion of pharmaceutical drugs are rarely reported to police and, even when they are, the offences are difficult to prove.

A further issue of concern for police is crime committed while under the influence of pharmaceutical drugs. This includes violent and property crime. Also problematic is crime committed to obtain pharmaceuticals. This includes:

- the forgery and alteration of prescriptions; and
- robberies and thefts from pharmacies, hospitals and points of wholesale, manufacture and transport.

Many of the responses required to reduce the misuse of pharmaceutical drugs are 'upstream' responses, which include measures such as enhancing the QUM. Nevertheless, if police are not given the appropriate tools to respond to the 'downstream' problems associated with those who are profiting from the illegal sale of these drugs, then this would be a major gap in Australia's strategic response to these problems.

Pharmaceutical drugs have historically not featured prominently on the 'policing radar' of illicit drug problems. This is, however, changing and pharmaceutical drugs are likely to become increasingly problematic in coming years (Nicholas, 2010).

Question 6

What role do police agencies and other law enforcement agencies have in responding to problems of pharmaceutical drug misuse?

Question 7

To what extent are pharmaceutical drug misuse problems impacting on policing agencies in different jurisdictions?

5 International Developments

The misuse of pharmaceuticals is a relatively recent international phenomenon. There has been a substantial global increase in consumption of prescribed opioids (Rintoul, Dobbin, Drummer and Ozanne-Smith, 2010), and among other substances such as benzodiazepines, amphetamines and OTC medications. The misuse of pharmaceutical opiates occurring in many developed countries represents a fundamental paradigm shift away from heroin as the opioid of choice (Fischer and Rehm, 2007). Moreover, the International Narcotics Control Board reported that use of and trafficking in prescription drugs exceeds that of illicit drugs in some countries (INCB, 2010).

5.1 North America

International trend data is drawn largely from the US, and to a lesser extent Canada. In 2002, Canada and the United States were among the highest consumers of controlled drugs worldwide (INCB, 2008). Between 2002 and 2006, the use of licit narcotic drugs increased by more than 80% in Canada and by more than 60% in the United States. Clearly not all of this increase is due to the problematic use of these drugs, as it could also be related to more aggressive treatment of painful conditions.

There are also indications of an increase in the level of misuse of pharmaceutical drugs in the US. In 2008, the Substance Abuse and Mental Health Services Administration (SAMHSA, 2008a) reported that a greater proportion of the American population misused prescription opioids than misused cocaine and heroin. In that year, pharmaceutical drugs were second only to cannabis in levels of misuse in the US. This is concerning because, as the INCB pointed out, there is a strong correlation between the extent of problematic use of various pharmaceutical preparations and their availability on the illicit market (INCB, 2008).

Between 1992 and 2002 the U.S. population increased by 13% and prescriptions for non-controlled drugs rose by 57%, but prescriptions for controlled drugs climbed by 154%. The largest increases in prescriptions for controlled drugs between 1992 and 2002 were for stimulants (369%) and opioids (222%) (National Center on Addiction and Substance Abuse, CASA, 2005).

In the US, the rate of increase of pharmaceutical misuse is highest among younger people (CASA, 2005 and SAMHSA, 2008b). Poisoning deaths involving opioid analgesics have also increased sharply in recent years. Between 1999-2007, for example, the number of US poisoning deaths involving any opioid analgesic (e.g., oxycodone, methadone, or hydrocodone) more than tripled, from 4,041 to 14,459. (Centers for Disease Control and Prevention, CDC, 2010). There has also been a substantial increase: in prescription drug-related emergency department visits (SAMHSA, 2008b); prescription drug-related deaths (Paulozzi, 2006); and in treatment demand (United Nations Office on Drugs and Crime, UNODC, 2010).

5.2 Other countries

Other countries have also experienced increases in the misuse of pharmaceuticals, and opioids in particular. In Eastern Europe and Central Asia the injection of opioids used for opioid substitution therapy (OST) is becoming an increasing problem. Some South Asian countries have also seen marked problems related to pharmaceutical

opioid misuse, and increasingly injection. In addition, pharmaceutical preparations containing controlled substances are easily obtained on unregulated markets in the Middle East and Northern Africa, with considerable unregulated sale of pharmaceuticals over the counter without prescriptions occurring (Degenhardt et al., no date).

While there has been an increase in the use of these prescription drugs in the European Union, in contrast with North America, the misuse of prescription drugs has not been generally regarded as a major problem in this region. This difference is at least partly due to the existing regulatory frameworks and prescribing practices, both of which differ from those of the US (European Monitoring Centre for Drugs and Drug Addiction, 2010).

In contrast, the INCB (2008) is also concerned about the undersupply of opioid analgesics to many developing countries. This significantly limits the capacity of those countries to effectively manage pain-related problems.

5.3 Summary

The situation in North America in particular provides many valuable lessons for Australia. That said, Australia has different regulatory approaches and major systemic differences to the US which are likely to influence the outcomes in this area.

Question 8

What can we learn from other countries' experiences with problems with, and responses to, pharmaceutical drug misuse?

Question 9

What, if any, unintended consequences might be expected in Australia if levels of access to medications such as opioid analgesics were to be reduced? What strategies could be put in place to avoid these unintended consequences?

6 The Situation in Australia

6.1 General population use

The 2007 National Drug Strategy Household Survey (Australian Institute of Health and Welfare, AIHW, 2008c) found that 7% of Australians aged 14 years and over had used pain-killers, tranquilisers, barbiturates and/or steroids for non-medical purposes in their lifetime and about half of these had done so in the past 12 months[3]. Pain killers/analgesics were used for non-medical purposes by 2.5% of the population in the past 12 months. In the same year, 1.3% of Australians aged 12 years or older had used tranquillisers or sleeping pills for non-medical purposes (AIHW, 2008b). Males were more likely than females to have used pharmaceuticals for non-medical purposes in their lifetime (7.6% versus 6.4%), but equal proportions of males and females (3.6%) had used these drugs in the past 12 months.

In 2007 Australians aged 20–29 years were more likely than other age groups to have used pharmaceuticals for non-medical purposes in their lifetime (10.3%), in the previous 12 months (5.4%) and in the previous month (2.4%). The AIHW (2008a) reported that Tasmania and the Northern Territory had the highest rates of nonmedical use of pain killers/analgesics. These two jurisdictions have historically had low availability of heroin and there is an apparent inverse relationship between heroin availability and levels of pharmaceutical opioid misuse (Fry et al., 2007).

Recent use of tranquillisers/sleeping pills declined from 3% of the Australian population aged 14 years and over in 1998 (Adhikari & Summerill, 2000) to 1.4% in 2007 (AIHW, 2008b).

6.2 Illicit drug users

Use and misuse of pharmaceutical drugs is very common among illicit drug users in Australia (Nielsen et al., 2008; Stafford & Burns, 2010). The most commonly used pharmaceutical drugs are opioids and benzodiazepines (Stafford & Burns, 2010). The use and injection of pharmaceutical opioids appears more common among injecting drug users in rural areas compared with metropolitan areas (Day et al., 2005). This is probably related to heroin availability (Fry et al., 2007).

6.3 Treatment and intervention settings

Recent data from the Sydney Medically Supervised Injection Centre (MSIC, 2010) indicates that opioids other than heroin are the most commonly injected drugs at the facility. From mid to late 2006 the percentage of injections of other opioids exceeded heroin and it now significantly exceeds the proportion of heroin injections.

Australia-wide, a significant and increasing proportion of people accessing needle and syringe programs (NSP) inject pharmaceutical opioids. In 2005, 9% of respondent NSP users indicated that their most recently injected drug was a

[3] Examples of pain killers/analgesics listed in the NDSHS questionnaire included aspirin, paracetamol, Mersyndol®, Panadeine Forte®, and Nurofen Plus®. As such, respondents may not have included other drugs such as oxycodone, or fentanyl in their responses, thereby understating the self-reported use of these substances.

pharmaceutical opioid (other than methadone, or buprenorphine). By 2009, this had risen to 16% (National Centre in HIV Epidemiology and Clinical Research, NCHECR, 2010).

Problematic misuse of pharmaceutical drugs now also features prominently in Australian alcohol and other drug treatment statistics. In 2008-09 the problematic misuse of morphine and methadone accounted for almost 20% of all publicly-funded treatment episodes for opioid problems (AIHW, 2010).

7 Opioids and Pain Management

The availability of pharmaceutical opioids has substantially increased in recent years (see Figure 2). Most notable is the exponential increase in the supply of oxycodone over the past 5-6 years and a concomitant decrease in pethidine since the late 1990s. Decline in per-capita consumption of pethidine reflects recognition that the drug has no therapeutic advantage over other narcotic analgesics and more toxic side effects (for example, see Clark, Wei & Anderson, 1995). Pethidine has also been removed from the PBS which has further contributed to a decline in its use.

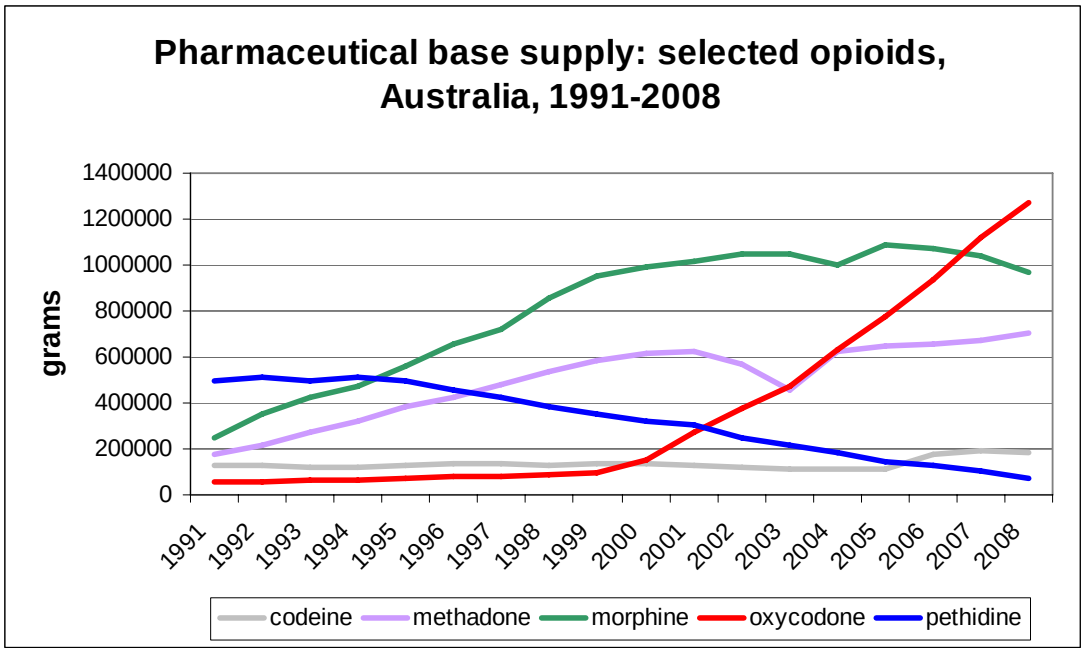

Figure 2. Pharmaceutical base supply: selected opioids 1991-2008

Source: Dobbin, 2009 p 2.

There has also been a steady increase in morphine supply to Australia and a dramatic increase in oxycodone supply (see Figure 2). Likewise Degenhardt et al. (2006) reported an 89% increase in the average number of milligrams of morphine prescribed per person aged 15–54 years between 1995 and 2003. Similarly, the Pharmaceutical Benefits Scheme (Department of Health and Ageing, 2008) reported a 20.1% increase in the prescription of oxycodone between 2005/06 and 2006/07 (1,087,412 and 1,306,152 annual prescriptions, respectively). In Australia, the supply of oxycodone increased from 95.1 kg in 1999 to 1270.7 kg in 2008 (Dobbin, 2009) - a 13 fold increase. Oxycodone supply to Victoria alone increased nine-fold from 7.5 mg per capita in 2000 to 67.5 mg per capita in 2009 (Rintoul, et al., 2010).

It is important to note that the increase in supply and use of these drugs is not, of itself, a negative outcome or directly indicative of problematic use. The increase in the level of supply/use could also be indicative of more widespread, clinically appropriate, use of these medications for painful conditions. It could also be a result of an increasing requirement for these medications, as a consequence of Australia's ageing population. The central issue is not so much the level of use per se, but rather the extent to which that level is consistent with the quality use of these medicines. It is imperative that this distinction is made. Otherwise, there is a risk of introducing

measures that aim to achieve a generalised *reduction in use*, rather than measures which seek to promote *quality use*.

The use of opioids in the treatment of acute pain (such as post-operative pain) and malignant (cancer) pain is relatively uncontroversial[4] (British Pain Society, BPS, 2010). So too is their use in opioid substitution therapy (Mattick, Breen, Kimber, & Davoli, 2009). These drugs have a long-established and well-understood role in these conditions. The longer-term use of opioids in the treatment of chronic non-malignant pain (CNMP) is more controversial and the subject of considerable debate in recent times. There is controversy regarding its long-term effectiveness and safety, particularly the risk of tolerance, dependence, or abuse (Noble et al. 2010). The extent to which longer acting opioids are prescribed for chronic non-malignant pain in Australia is unclear, but in America 95% of these drugs are prescribed for CNMP (RACP, 2009).

Broadly, there are two issues of concern regarding the prescription of opioids for CNMP. The first issue relates to whether long-term prescribing of opioids for CNMP is clinically sound and beneficial. The second is the extent to which the expanded prescription for CNMP has facilitated diversion for use by persons other than those for whom these drugs were prescribed.

A challenge in establishing the efficacy of opioids in the long term management of CNMP is the difficulty entailed in conducting double blind studies in this area, due to the impracticality of providing placebo drugs to patients in pain. Also problematic is the heterogeneity of the patient population (RACP, 2009).

Available research concludes[5] that:

- opioids can be effective compared to placebo in the treatment of CNMP over short periods, being associated with reduced pain and improved functional outcomes;
- appropriate management of opioid therapy in well-selected patients with no history of substance dependence or misuse can lead to longer-term pain relief for some patients with a very small risk of developing dependence, abuse, or other serious side effects;
- the evidence base concerning the efficacy of opioids in the longer term treatment of CNMP is weak and inconclusive but they are more effective than placebo;
- opioids are better for reducing pain than for improving function;
- strong opioids (oxycodone and morphine) are statistically superior to some anti-inflammatory and antidepressant drugs for pain relief but not for functional outcomes;
- weak opioids (propoxyphene, tramadol and codeine) do not significantly outperform non-steroidal anti-inflammatory drugs or tri-cyclic anti-depressants for either pain relief or functional outcomes; and
- many patients discontinue long-term opioid therapy (especially oral opioids) due to adverse events, or insufficient pain relief.

In short, there is considerable doubt over the efficacy of opioids in the longer term treatment of CNMP. Where they are used, there is a need for a thorough assessment to determine patients' risks of substance misuse. Given the extent to which these

[4] That said, there is no particular reason to believe that having a malignant disease precludes patients from misusing or on-selling their opioid medication.
[5] For a fully referenced review of the literature concerning this issue, the reader is referred to the complete literature review available at http://www.nceta.flinders.edu.au/

medications are used in the treatment of CNMP in Australia, there appears to be a considerable evidence-practice gap.

As noted above, there is a need for a thorough assessment of patients prior to commencing opioids and the application of the framework of universal precautions to the area of pain management. In utilising this framework, all patients who are being considered for opioid therapy, are screened for past or present substance misuse problems, or psychiatric disorders and extra support is provided to those at risk (Gourlay, Heit, & Almahrezi, 2005).

This approach highlights:

- the importance of a comprehensive substance use history and family history to identify people at risk of developing problems;
- the usefulness of urine drug toxicology to assist in identifying at-risk patients;
- a treatment agreement based on informed consent regarding the risks of dependence; and
- clear boundaries surrounding the use of opioids (RACP, 2009).

Under this approach, the use of opioids for chronic pain is used on the basis of a trial of their usefulness, and subject to ongoing evaluation. This approach has potential for prevention and early identification of problematic opioid use as well as appropriate 'triage' into levels of specialist care as needed, including pain and addiction specialist care. It may have particular utility for GPs (RACP, 2009).

Question 10

To what extent is there a current evidence/practice gap in Australia concerning the use of opioids for CNMP?

8 Benzodiazepines and Their Role in Treating Insomnia and Anxiety

There have also been important changes in the patterns of benzodiazepine prescribing in recent years.

Table 1. Pharmaceutical Benefits Scheme prescriptions for benzodiazepines 2002-2009

	Diazepam	Oxazepam	Temazepam	Alprazolam*	Total
2002	1,576,635	1,220,936	2,237,733	324,110	5,359,404
2009	1,639,952	1,015,080	1,840,222	413,526	4,908,780
% change	+4%	-17%	-18%	+28%	-8%

*Private or non-PBS prescriptions for alprazolam comprised on average an additional 32% of prescriptions per year, based on estimates from the Australian Statistics on Medicines.

Source: Australian Government published PBS data cited in Monheit, 2010.

Table 1 shows the substantial reduction in the overall number of PBS prescriptions for benzodiazepines between 2002 and 2009, but a substantial increase in prescriptions for alprazolam. The misuse of alprazolam is particularly problematic from a range of perspectives. It appears to be disproportionately associated with problems such as seizures and rage responses among users, as well as traffic accidents and crime-related harms (Nielsen, et al. 2008 and Drugs and Crime Prevention Committee, of the Parliament of Victoria, DCPC, 2007).

Several prescription guidelines are available to assist in the prescription of benzodiazepines for insomnia. The National Prescribing Service, for example, suggests avoiding prescribing hypnotic medicines whenever possible. If this is not possible, a short-acting benzodiazepine (e.g. temazepam) or other related drug (zolpidem or zopiclone) should only be considered if:

- immediate short-term symptom relief is required;
- sleep difficulties are expected to be short-lived (acute insomnia) and non-drug therapies cannot be implemented readily; or
- chronic insomnia has not responded to non-drug therapies alone.

The NPS suggests that if benzodiazepine treatment is required, then this should occur for less than two weeks and ideally intermittently (e.g. 2–5 nights per week). For patients already on longer term benzodiazepine treatment, actively pursuing discontinuation is suggested.

Benzodiazepines are no longer considered the first-line treatment for anxiety conditions. Psychological therapies can be at least as effective as drug therapies in the treatment of anxiety disorders and should be considered first-line responses in the treatment of anxiety if accessible, acceptable to the patient and appropriate to the severity of impairment. Where pharmacological therapies are required, selective serotonin reuptake inhibitors (SSRIs) are the preferred medication given the strength of evidence indicating their use and because they are well tolerated by patients (Western Australia Psychotropic Drugs Committee, 2008).

There is a significant issue in Australia with the large numbers of patients (particularly among the elderly) who are currently using benzodiazepines and who have been doing so for a long time. The withdrawal from these drugs, where feasible, can be very difficult and requires careful management.

The extent to which benzodiazepines are currently prescribed in Australia also suggests a significant gap between current practices and best practice in the prescription of these drugs. In short, there appears to be a need to redefine the therapeutic applications of benzodiazepines towards much shorter-term use.

Question 11

To what extent is there a current evidence/practice gap in Australia concerning the use of benzodiazepines for conditions such as anxiety and insomnia?

9 Evidence of Harms

9.1 Health harms from opioids

A range of harms can stem from the misuse of opioids. These include:

- sedation, leading to respiratory depression and ultimately death in overdose;
- the development of tolerance and withdrawal syndromes;
- adverse consequences following the injection of drugs intended to be taken orally;
- hyperalgesia;
- effects of longer-term opioid use, such as reductions in bone density (for example see Kinjo, Setoguchi, Schneeweiss & Solomon, 2005).

A major harm associated with the misuse of opioids is overdose or poisoning. The Australian Institute of Health and Welfare (AIHW) provides information about hospital treatment of poisoning[6] which is presented diagrammatically below. Since 1998-99 the number of hospital separations for poisoning with heroin has decreased and that for opioid analgesics has increased, with a substantial acceleration in the rate of increase from 2005-06. Poisoning involving other opioids increased from 33% of all opioid poisoning hospitalisations in 1998-99 to 80% in 2007-08. It is not possible from this data to distinguish the proportion of separations for opioid analgesics attributable to problematic use by those seeking intoxication, from those arising as an adverse effect of their therapeutic use to treat pain.

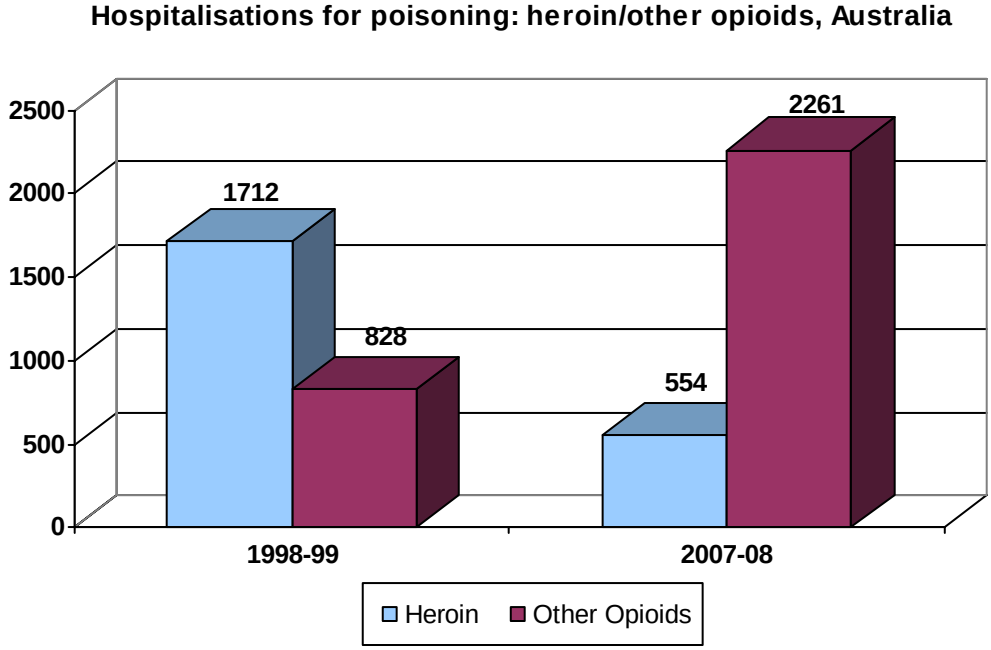

Figure 3. Hospitalisations for poisoning: heroin and other opioids, Australia

Source: Dobbin (2009 p 13).

[6] AIHW National Hospital Morbidity Database. http://d01.aihw.gov.au/cognos/cgi-bin/ppdscgi.exe?DC=Q&E=/AHS/pdx0708. Accessed 18 October 2009.

Rintoul et al. (2010) also found that the detection of oxycodone in deaths reported to the Victorian Coroner increased from 4 (0.08/100,000 population) in 2000 to 97 (1.78/100 000 population) in 2009. The authors found that drug toxicity deaths were overrepresented in rural areas and areas with high levels of disadvantage. They concluded that the increase in the number of deaths involving oxycodone was strongly and significantly associated with the increase in supply.

9.2 Health harms from benzodiazepines

Harms that can arise from use of benzodiazepines include:

- sedation, particularly at high doses, which can contribute to concentration and memory problems and to chaotic behaviour and disorganisation;
- anterograde amnesia when the memory of events occurring after taking benzodiazepines is affected, whilst long-term memory remains intact;
- contribution to overdose when consumed with other central nervous system drugs (CNS) drugs;
- dependence can occur quickly and the benzodiazepine dependence syndrome is very difficult to treat;
- paradoxical aggression or the so called 'Rambo effect' - while benzodiazepines are frequently prescribed for their tranquillising effect in the relief of insomnia and anxiety, paradoxically, they can trigger incidents of CNS stimulation, which manifests as talkativeness, mania, anxiety, restlessness and sleep disturbances and nightmares; and
- adverse impacts on driving (DCPC, 2007).

A significant problem associated with benzodiazepines, particularly in the elderly, is falls and other injuries (Bartlett et al., 2009). The combined use of benzodiazepines and illicit drugs can also have adverse outcomes. For example, Woods, Gerostamoulos and Drummer (2007) found that of the heroin-related deaths that occurred in Victoria between 2002 and 2006, 55% involved benzodiazepines.

As was discussed above not all benzodiazepines are equally associated with harm. Alprazolam in particular appears to be associated with a disproportionately large number of problems.

9.3 Other harms

It is possible that a large, but currently unquantifiable, number of people without a history of injecting drug use may have escalated their use of pharmaceutical drugs beyond recognised therapeutic doses. Such individuals may have also developed related problematic behaviours, including drug-seeking from multiple prescribers and pharmacists. There is little information about this 'hidden' population, because they are not captured by any current research, unlike injecting drug users where information about unsanctioned use of prescription opioids is relatively well described (RACP, 2009).

The harms associated with pharmaceuticals are not confined to prescription drugs. Over the counter or non-prescription drugs are also an emerging problem. Foremost among these are codeine-containing analgesics especially those containing paracetemol or ibuprofen. Complications associated with the misuse of these drugs

include gastro-intestinal bleeding and/or perforation, renal failure, low potassium levels, anaemia, opioid dependence and death (Dobbin, 2008).

One of the key issues in relation to the problematic misuse of pharmaceutical drugs is that they are often administered in ways unintended by the prescriber and manufacturer. Medications can be crushed or chewed and taken orally so as to circumvent slow release formulations. They can also be crushed and then snorted or injected to increase the rate of absorption. In addition they can be stockpiled and taken in large quantities to increase the effect (Sproule, Brands, Li & Catz-Biro, 2009).

The injection of pharmaceutical drugs, particularly those intended for oral administration, is especially problematic. It can lead to infections as a result of unsterile injection processes, deposition of pharmaceutical materials in blood vessels or organs, or the occlusion of blood vessels or organs (DCPC, 2007).

A range of measures have been introduced to reduce the harms associated with the injection of medications intended to be taken orally. These include the provision of:

- specifically designed filters (or at least cotton wool for filtering processes);
- large bore syringes for injection;
- sterile water; and
- spoons (Anex, 2007, as cited in DCPC, 2007).

Hence, it is not just that pharmaceutical drugs are taken in dosages, or by persons, not intended by prescribers, it is also that the drugs can be taken in ways that were not intended by prescribers, dispensers and manufacturers.

9.4 Policing implications

There is also evidence of increasing levels of detection of pharmaceutical-related offences by policing agencies in Australia. Data compiled by police jurisdictions to support the development of the NPDMS, indicate that there has been an increase in the number of police detections and seizures of pharmaceutical drugs over the past decade. There was an overall increase in police detections of opioid pharmaceutical drugs over this period, while the number of seizures of benzodiazepines has been stable or has declined. In addition, opioids are now the most commonly seized/detected pharmaceutical drug in most of the jurisdictions that were able to provide data.

These data are likely to significantly under-estimate the extent of impact of pharmaceutical drug misuse on policing. This is because the difficulties associated with detecting and proving offences is likely to lead to under-reporting.

There also appear to be links between the use and misuse of pharmaceuticals and offending, given the disproportionately large number of police detainees who test positive for opioids and benzodiazepines. The 2008 Drug Use Monitoring in Australia (DUMA) survey of police detainees noted that 15% of adult detainees who provided a urine sample tested positive for an opiate metabolite not identified as heroin[7]. Eleven percent of female detainees and five percent of male detainees tested were positive for methadone. Of those who tested positive, 34% reported having used methadone illegally. Eight percent of tested adult detainees were positive for buprenorphine. In addition, 23% of detainees who provided a urine sample in 2008 tested positive for

[7] This could have been a prescribed opioid or an OTC opioid.

benzodiazepines. Urinalysis does not differentiate between prescribed and non-prescribed use of prescription drugs. Consequently, detainees were asked to report if, in the past fortnight, they had taken any medication prescribed for them. In 2008, 21% of detainees reported that they had taken benzodiazepines prescribed for them in the past fortnight. Of this group, one in four also reported using non-prescribed benzodiazepines in the past 30 days (Gaffney, Jones, Sweeny, & Payne, 2010).

Question 12

Is there other evidence of harms stemming from pharmaceutical misuse?

Question 13

Certain groups in the community (such as those living in rural areas and those experiencing social disadvantage) appear to be disproportionately affected by levels of harm associated with pharmaceutical drug-related problems. What could be done to address this in a targeted way?

10 Who Misuses Pharmaceutical Drugs in Australia?

Before focussing on the misuse of these pharmaceutical drugs, it is important to emphasise that they are also widely and appropriately used in the community and can bring great benefits to their consumers. The fact that they are also subject to misuse in no way detracts from these benefits. This emphasises the importance of their continued clinically appropriate availability in the absence of any associated stigma.

Nevertheless, a wide range of individuals misuse pharmaceuticals in a diverse range of contexts. As Wodak and Osborn pointed out in their submission to DCPC (2007):

> *It is important to separate out the very different problems arising in different age groups and populations in terms of developing effective interventions. Very different problems arise in quite different settings [such as] young polydrug users; middle aged people with severe chronic illnesses; and the elderly* (p. 6).

Three profiles of patients who may attempt to access prescription drugs illegitimately have been described (Galloway, in DCPC, 2007).

1. **The dependent patient** who may have genuine pain problems.
2. **The drug misuser** who has a history of drug misuse but also may have some evidence of pain.
3. **The drug seller** who attends doctors with the primary aim of obtaining drugs to sell or trade.

There is a wide spectrum of patients covered in this typology. Dependent patients, for example, may be deliberately or inadvertently misusing their medications. They may have developed an inadvertent iatrogenic dependence as a result of factors such as inappropriate prescribing, limited health literacy, poorly worded medication instructions or poor communication by health care providers. Patients misusing their medications may also ‘use a bit and sell a bit’ or they may be obtaining their medications exclusively for resale.

A spectrum of non-adherence with opioid treatment is apparent and this spectrum is distinct for pain patients versus those who use these medications for nonmedical purposes (see Figure 4). Non-medical users can be seen as self-treating for personal issues, purely recreational users, or as having a more severe and consistent substance use disorder or dependence. On the other hand, pain patients are more complex and their behaviours might range from strict adherence, to chemically coping, to an overt dependence (Passik & Kirsch, 2008).

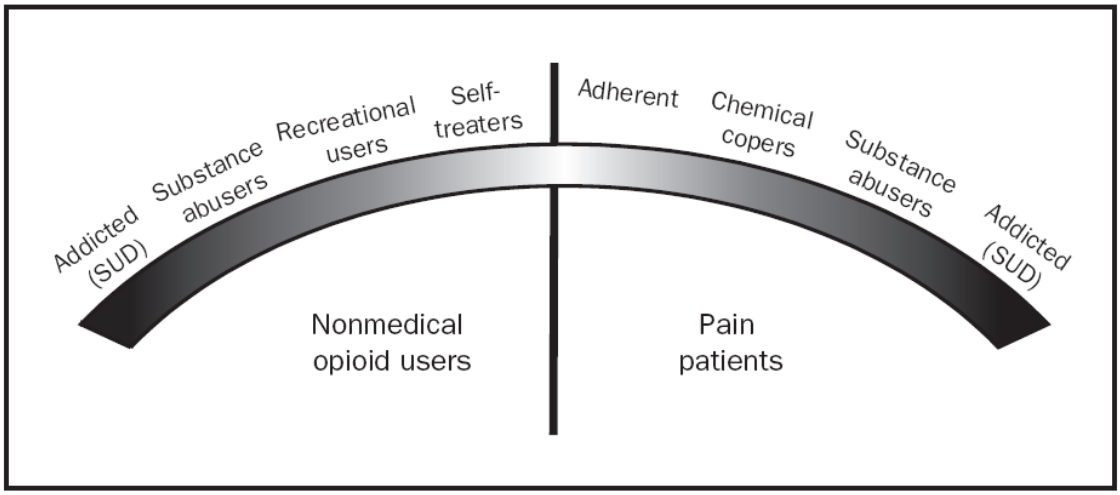

Figure 4. The spectrum of adherence for pain patients versus the spectrum of illicit use by nonmedical users

Source: Passik and Kirsch (2008 p. 401).

In addition to those who are intentionally misusing opioid or benzodiazepine medications, there is likely to be a large number of Australians using these medications as prescribed but where those prescriptions do not represent a quality use of those medicines. Patients may have been using these medications for some time and, particularly in the case of benzodiazepines, withdrawal from them may be very difficult.

11 How are the Drugs Obtained?

11.1 Methods

The DCPC (2007) described a range of ways in which pharmaceuticals intended for misuse might be obtained. These included:

- medication shopping (presenting to several pharmacies / doctors and obtaining prescriptions drugs for imaginary or exaggerated symptoms);
- stealing, forging or altering prescriptions;
- burglaries of surgeries and pharmacies and private homes;
- the prescription of drugs in larger quantities than are needed for managing a patient's condition, providing an opportunity for the patient to sell the excess;
- purchasing on the black market or on the Internet; and
- health workers self-prescribing or otherwise misappropriating drugs through their work.

There is also a range of supply-side dynamics that impact upon the ways in which these medicines are obtained for misuse. Poor prescribing practices, in which patients are prescribed levels of medications well in excess of their medical need, undoubtedly contribute to this. Also important in this regard are poor dispensing practices, in which some pharmacists knowingly dispense levels of medications to individuals which are also in excess of medical need. Despite the presence of a valid prescription, pharmacists also have a responsibility to contribute to the QUM by not knowingly dispensing excess medications.

11.2 The illicit sale of pharmaceutical drugs

The diversion and illicit sale of pharmaceutical drugs in Australia can be very lucrative. The drugs are available at subsidised rates on the PBS and can be on-sold at considerable profit.

An important emerging illicit supply side dynamic, is that of organised illicit medication entrepreneurs who obtain large amounts of the medications wholly, or largely, for profit. This may involve visiting large numbers of prescribers and pharmacists, sometimes across several jurisdictions, to obtain opioids and other drugs. These are then on-sold in the community for substantial profit.

Unfortunately it is not always necessary for these individuals to visit multiple doctors and pharmacies in order to obtain these drugs. At times, large amounts of these drugs have been prescribed by the same doctor and dispensed from the same pharmacy. Overall, the evidence strongly suggests that most misused prescription medications are obtained directly from prescriptions provided by health practitioners (Rodwell, Ringland & Bradford, 2010; Fry et al. 2007).

In summary, the profit to be made from the illicit sale of pharmaceuticals is likely to be a significant incentive for their diversion.

11.3 Medication shopping

One of the most overt and problematic manifestations of consumer demand for pharmaceutical products is in the form of 'doctor shopping' or more precisely 'medication shopping'. This refers to the process of individuals visiting several prescribers and/or pharmacies with the aim of obtaining multiple prescriptions/medications in quantities greater than their therapeutic need. The drugs may be for personal use and/or diverted onto the illicit drug market.

Fountain et al. (1998) and others have identified a number of ways in which medication seekers obtain multiple prescriptions, including: exaggerating dependency or other symptoms; gaining sympathy; bargaining; feigning dependence; presenting to prescribers where they are not known; using altered or stolen prescriptions; and the acquisition from family and friends. Thomson et al. (2008) reported that 'pharmacy shopping' was a common strategy used by illicit drug users to obtain larger than required amounts of codeine products. Many respondents also noted that they often ask family or friends to purchase OTC codeine products on their behalf.

Medicare Australia uses the term 'prescription shopper' to refer to anyone who, within any 3 month period, has had supplied to them PBS items prescribed by 6 or more different prescribers (including nurse practitioners and midwives but excluding specialists and consultant physicians); and/or a total of 25 or more target PBS items; and/or a total of 50 or more PBS items (Medicare Australia, 2011).

Relatively large numbers of people have been identified as prescription shoppers by the Medicare Australia Prescription Shopping Program. In 2005-06 there were close to 55,000 such individuals identified[8] (cited in Dobbin, 2011, p9). Medication shoppers also account for significant proportions of all prescriptions filled on the PBS. In a submission to the DCPC (2007), Dobbin, using unpublished data from the PBS, noted that between 5% and 20% of all prescribed codeine preparations, and between 4% and 16% of all prescribed benzodiazepine preparations, were prescribed to people who had been identified as 'prescription shoppers'.

The Prescription Shopping Program has a number of limitations. Some are similar to those that apply more generally to PBS data, namely:

- that data is only collected on medications which are eligible for a PBS benefit and where the pharmacist requires re-imbursement from the PBS. These data do not include those who are receiving non-PBS medications (including private prescriptions and those administered by other bodies, such as Transport Accident Commission (TAC) and Department of Veterans Affairs (DVA), or medicines below the cost of PBS subsidies. It also does not capture those who may be using multiple identities or Medicare cards;
- this system will not detect those visiting multiple pharmacies for OTC codeine preparations;
- the threshold to meet the Medicare Australia prescription shopping criteria is high and potentially means that many people at risk because of over or improper use of medication are not captured by these data or the systems that these data inform;
- the data is collected retrospectively;
- there is a lag time after the data is available during which the data is analysed; and

[8] It is important to note that this figure includes people who exceed the thresholds set by Medicare Australia but whose medicine usage is clinically appropriate.

- prescribers must be registered to use the system and pharmacists cannot access the system at all.

It is also important to note that, in the case of inappropriate prescribing patterns, it may not be necessary for patients to visit multiple prescribers in order to obtain amounts of medications which are well in excess of their medical needs.

The extent of medication shopping via local and overseas online pharmacies is unknown (Nielsen & Barratt, 2009) as is the type of drugs purchased through these pharmacies (St George et al., 2004). Australia has a well-developed range of mechanisms which control the sale and supply of pharmaceuticals. Online pharmacies, however, are subject to the laws of the countries in which they are based. Online pharmacies are likely to be a relatively small slice of the current pharmaceuticals market and are unlikely to overtake traditional sources of medication supply in Australia in the immediate future. The existence of particular overseas online pharmacies, such as those based in Mexico and Thailand, nonetheless raise important issues at the consumer level about access and quality.

Question 14

To what extent is Australia's Prescription Shopping Program able to impact on the misuse of pharmaceuticals?

12 Other Issues Impacting Upon the Quality Use of Pharmaceutical Opioids and Similar Medications in Australia

A range of other issues impact on the quality use of these medications. Some of these are addressed below.

12.1 The lack of uniformity and comprehensiveness in regulatory and monitoring approaches across Australian jurisdictions

There is currently a diversity of approaches across Australian jurisdictions in regard to the regulation and monitoring of medications in general and Schedule 8 drugs in particular. Monitoring programs are particularly important in this regard. Prescription Monitoring Programs (PMPS) and Coordinated Medication Management Systems (CMMS) are surveillance measures that record the prescription and/or dispensing details of defined prescription drugs. They are either paper-based, or increasingly electronic and real time data-monitoring processes. They are designed to identify irregularities in agreed treatment (such as excessive prescription amounts or early repeat dispensing and medication shopping). They are used as a basis for implementing investigation and/or enforcement measures (Fischer, Bibby & Bouchard, 2010).

The lack of CMMS in most jurisdictions means prescribers have no means of knowing if patients are seeing other prescribers and what other drugs they are taking. Equally in most jurisdictions, pharmacists have no means of accessing information concerning the full extent of the drug use of their patients. This is further complicated by the national registration of health professionals (described below), whereby many prescribers can write prescriptions which can be filled in other jurisdictions.

Dobbin (2010) described the four generations of PMPs.

1. The first generation involves inspection by regulatory authorities of copies of filled prescriptions retained at pharmacies.
2. The second generation involves paper-based collation of prescriptions sent from pharmacies to a centralised point to be analysed by regulatory staff and decisions are then made about the need to communicate with prescribers and/or pharmacists about problematic patients or prescribers.
3. The third generation involves the electronic transmission of prescription information but not in real time.
4. The fourth generation is best described as a CMMS as it is far more coordinated and involves the instantaneous or real-time transmission of prescription information to prescribers, pharmacists and regulators. For a CMMS to be successful, it is important that it is underpinned by a sound clinical regulatory framework which has as its basis the QUM.

Most Australian jurisdictions utilise first, second and third generation PMPs, with Tasmania moving towards finalisation of a fourth generation CMMS at the time of writing. Each generation of PMP is more effective than its predecessor (Dobbin, 2010).

International evidence suggests that:

- merely monitoring the prescription of controlled drugs reduces prescription rates;
- early generation PMPs risk leading to 'chilling effects' or 'substitution effects' on appropriate prescribing;[9] and
- CMMSs, on the other hand, monitor the prescription practices of prescribers while providing them with real time information on the medication use of their patients which empowers prescribers to enhance the quality use of medicines.

The implication of this for Australian jurisdictions with generation one and two PMPs, is that there is little advantage to be gained in upgrading their systems to generation three PMPs. In short, the major advantages stem from upgrading to a CMMS. The absence of such a system is likely to adversely impact the quality use of medications in Australia. A CMMS would have a range of benefits including the ability to:

- identify prescribers with limitations on their practices;
- identify potential drug interactions and contra-indications;
- identify medication duplication via multiple prescribers; and
- block reported stolen/forged/altered prescriptions.

Question 15

How effective is Australia's current approach to the regulation and monitoring of these medications and how could the current approach be improved?

Question 16

What are the key issues that arise concerning the balance between measures which are intended to enhance the quality use of medicines (such as a CMMS) and the needs to protect the privacy of patient information?

Question 17

Are there any measures that could be introduced in the short term that would enhance our ability to monitor the prescription and dispensing of these medications?

12.2 The ability of patients to access many different prescribers and pharmacists

The structure of Australia's health care system means patients are free to choose their prescribers and pharmacists. In the absence of structures linking prescribers, pharmacists and regulators, these groups are often not in a position to know the full extent of patients' medication use. This can not only lead to opportunities for the deliberate misuse of these medications, but may facilitate inappropriate prescribing and adverse medication interactions.

[9] 'Chilling effects' refer to a reduced preparedness on the behalf of prescribers to prescribe controlled drugs even when these are clinically appropriate. 'Substitution effects' refers to prescribers using alternatives to controlled drugs which are potentially less appropriate. These effects occur because under these early generation programs, prescribers are monitored without being given the tools to gain a comprehensive picture of the medications their patients are taking.

12.3 The National Health Practitioner Registration

In July 2010, the state based system of registration for health practitioners was superseded by the national Australian Health Practitioner Regulation Agency (AHPRA). AHPRA is responsible for the registration and accreditation of 10 health professions across Australia, including the medical, dental, pharmacy, podiatry and nursing professions. Consequently the authority to prescribe drugs (registration) is controlled nationally while the monitoring and regulation of prescribing occurs at the jurisdictional level. Up until recently, prescriptions for S8 drugs written in one jurisdiction were unable to be filled in another jurisdiction. This has changed since the introduction of AHPRA, with prescriptions from all jurisdictions able to be filled in most (but not all) other jurisdictions. This has a range of implications for monitoring, regulation and cross-border prescription of controlled drugs.

12.4 The development of clinical guidelines

A range of guidelines are already in place internationally to assist prescribers with measures designed to enhance the quality use of medicines. Most relevant in the context of the NPDMS are those surrounding the prescription of opioids and benzodiazepines. These too, need to be taken in consideration in the development of the NPDMS along with the range of difficulties that are associated with the implementation of clinical guidelines. Of particular importance in this regard are the guidelines produced in Australia by Therapeutic Guidelines Ltd and the Australian and New Zealand College of Anaesthetists Faculty of Pain management.

12.5 The ageing of Australia's population in general and opioid substitution clients in particular

Australia has an ageing population as a result of sustained low fertility and increasing life expectancy. This is significant in the context of the problematic misuse of pharmaceutical drugs because the prevalence of a range of conditions including chronic pain increases as the population ages. Anxiety problems peak in middle age. As the prevalence of these conditions increases, this could also be expected to increase the demand for pharmacological responses to these problems.

The number of Australians receiving opioid substitution treatment is much larger than a decade ago. This group already experiences a higher prevalence of chronic pain than the general population and is also ageing and therefore entering a stage of life when pain is more prevalent. Long term exposure to opioids can also make pain treatment more complex. In addition, this group already has a high prevalence of pharmaceutical drug misuse. This is a complex issue that will require quite specific consideration in the Strategy.

12.6 Prescriber remuneration patterns

The current pattern of remuneration for prescribers may make it undesirable, or unviable, for them to utilise non-pharmacological treatments for conditions such as anxiety, insomnia and chronic non-malignant pain.

Question 18

How are the current prescriber remuneration patterns impacting on patterns of pharmaceutical drug misuse?

12.7 Opioid substitution therapy (OST) options, accessibility and dispensing fees

An issue which may also be impacting on pharmaceutical misuse is the accessibility and available range of OST for opioid dependent individuals. If OST is not readily accessible, either in terms of an individual being able to gain a place on an OST program, or the ease with which individuals can avail themselves of the program, then this could act as a barrier to its uptake. In this case, obtaining opioid medications from other prescribers, or illicitly, could present fewer difficulties compared with being on OST. This, in turn, could enhance the misuse of pharmaceutical opioids.

A further issue is that the cost of the OST drugs is funded by the Australian Government, but there is a dispensing fee that is not subsidised. This fee is therefore highly likely to adversely impact on entry into and retention in OST (Ritter & Chalmers, 2009). This cost also potentially provides an incentive to obtain other PBS opioid medications which may be cheaper.

Question 19

To what extent is OST accessibility and dispensing fees impacting on patterns of pharmaceutical drug misuse?

12.8 The availability of adjuvant drugs on the PBS

Adjuvants are medications often used in the management of persistent pain, although their usual role is for conditions other than pain. Examples include the anti-epileptics gabapentin and pregablin and the serotonin-noradrenaline (norepinephrine) reuptake inhibitors (SNRIs). These drugs are not approved for prescription under the PBS for the relief of pain. This contrasts with a range of opioids which are approved for this purpose. Therefore there is a disincentive to prescribe these drugs because patients would have to pay the full un-subsidised price.

Question 20

To what extent are the current patterns of availability of adjuvant drugs impacting on patterns of pharmaceutical drug misuse?

12.9 Difficulties in accessing specialised pain treatment

Australians can experience significant delays in accessing specialised pain clinics, particularly in the public health system. In addition, many CNMP patients are not referred to specialist services at all. This means that these patients may not receive comprehensive assessment of, and intervention for, their pain conditions. This could

mean that patients commence opioid treatment before an adequate trial of alternative therapies has been undertaken. This may also be a factor in enhancing the likelihood of the use of pharmacological treatments for pain conditions.

Question 21

To what extent are these difficulties impacting on patterns of pharmaceutical drug misuse?

12.10 The hospital to community transition

A further issue is that of psychotropic medications being prescribed for acute conditions while in hospital and the use of these medications continuing once the patient returns home. If patients' medications are not reviewed on their discharge from hospital then the use of these medications can continue long after the clinical indications for their use have subsided. This can lead to the development of an unwitting dependence on them. This can be compounded if hospitals provide a full packet of these medications on discharge that are significantly in excess of medical need.

Moreover, early discharge from hospital places greater reliance on GPs and primary care services to maintain medication regimes post-discharge. Appropriate medication management, especially where substances with abuse and dependence potential are involved, is an imperative.

Question 22

To what extent are problems with hospital to community transitions impacting on patterns of pharmaceutical drug misuse?

12.11 The marketing of medications

Pharmaceutical companies spend considerable sums of money to market their drugs to prescribers. Australia adopts a self-regulatory approach to this marketing with the relevant Code of Conduct being administered by Medicines Australia, the peak industry body. This marketing is most likely to occur for drugs during the period that they are under patent to the pharmaceutical companies because this is the time when they are most profitable. The impact of this on prescribing practices is unclear, but one aspect of the development of the NPDMS will be a consideration of whether the current self-regulatory approach is sufficient.

Also important in this regard is the potential for medications to be approved for use in Australia without sufficient consideration being given for their misuse potential.

12.12 Access to specialist addiction treatment services designed to meet the needs of non-injecting drug misusers

A proportion of those individuals misusing medications including opioids and benzodiazepines will need specialist drug treatment services. Australia currently has a shortage of specialist addiction physicians (Hotham, Roche, Skinner, & Dollman, 2005), which can impact on their accessibility. It is also not clear whether Australia's drug treatment services are appropriately oriented to meet the needs of misusers of pharmaceutical drugs who are not also injecting drugs users. If treatment services are developed, or reoriented, to meet the needs of this 'new' group of drug misusers, it will be important that this does not further stigmatise the existing group of illicit drug users with a history of injecting drugs. This is a further issue that warrants consideration in the development of the NPDMS.

12.13 The national Return of Unwanted Medications (RUM) Project

The RUM project is an important mechanism through which unwanted and out-of-date medicines are collected from consumers in Australia. It is managed by the National Return and Disposal of Unwanted Medicines Ltd and is funded by the Australian Government Department of Health and Ageing. This project acts to reduce the availability of medicines for accidental or intentional misuse. A secondary benefit of the Program is that it provides an insight into patterns of wastage of pharmaceutical drugs in Australia.

The program collects some 400 tonnes of unwanted medicines annually, which provides some indication of the significant level of unwanted and out of date medications in the community.

13 Potential Strategy Responses

In developing the NPDMS a wide range of issues will need to be addressed. Six main non-mutually exclusive areas of response to Australia's pharmaceutical misuse problems are outlined below, namely:

1. infrastructure, research, monitoring and system issues;
2. clinical responses;
3. harm reduction measures;
4. workforce development responses - including guidelines;
5. consumer responses - including enhancing health literacy;
6. technological responses; and
7. market forces and commercial aspects issues.

This is not intended to be an exhaustive list of possible responses. As indicated previously, the NPDMS will be informed by Australia's approach to quality use of medicines and the broader National Medicines Policy. An effective strategy is likely to require contributions from consumers, practitioners, providers and educators, the medicines industry and governments.

13.1 Infrastructure, research, monitoring and systems issues

13.1.1 A Coordinated Medication Management System (CMMS)

Australia's capacity to monitor the prescription and supply of controlled and other medications may be enhanced by the implementation of a CMMS which is based around the need to enhance the QUM. Prescribers' decisions about prescribing need to be made in the context of understanding patients' medication history, behavioural patterns and any concerns in relation to the potential for dependency problems. This substantially reduces the risks of inappropriate prescribing.

There may also be some benefit in incorporating the International Statistical Classification of Diseases and Related Health Problems into the CMMS to classify the diseases and the wide range of symptoms for which these drugs are prescribed. This information could be stored in the CMMS and protected by security access and could form the basis of important research into many conditions.

It is important to note, however, that the implementation of a national CMMS in Australia will not address all of the difficulties associated with the misuse of pharmaceutical drugs.

Question 23

To what extent would a CMMS enhance the QUM in Australia?

13.1.2 Data collection and sharing processes

Accurate, reliable and comprehensive data is required to facilitate a better understanding of, and informed responses to, pharmaceutical drug misuse in Australia. Also important is data interpretation and the ability to share data among relevant agencies such as health and regulatory agencies and, where appropriate, law enforcement agencies.

Question 24

How could Australia's data collection and sharing processes in this area be enhanced?

13.1.3 Focussed research

Areas of research which may inform discussion regarding a number of aspects of pharmaceutical misuse in Australia include:

- the extent and nature of pharmaceutical misuse, particularly among those who do not inject their medications;
- investigating the dynamics behind existing prescribing patterns to determine where prescribers could be better supported (for example in situations where prescribers may be intimidated by patients demanding medication);
- examining the extent to which the dynamics of regulatory and monitoring systems (see section 12.1 above) impact on pharmaceutical drug misuse and how this could be addressed;
- examining the characteristics and needs of new cohorts of illicit pharmaceutical drug misusers and the extent to which drug treatment facilities in Australia cater for the needs of clients who primarily misuse pharmaceutical medications;
- examining the impact of the diversion of pharmaceutical drugs on illicit drug markets and on crime;
- examining emerging illicit pharmaceutical drug markets; and
- examining the extent of 'off label' prescribing[10] and potential measures to address this.

As noted above, addressing many of these questions will require access to relevant data sources.

Question 25

Are there any other gaps in the research?

13.2 Clinical responses

There are a number of levels at which enhancements in clinical practice could reduce the over-prescribing and misuse of pharmaceutical drugs. At the macro-level, these include:

- an enhanced emphasis on initial accurate diagnosis before consideration is given to commencing these medications;

[10] This refers to the prescription of medications under the PBS for conditions for which they are not approved. This, again, is not in keeping with the quality use of medicines.

- improved multi-disciplinary approaches to conditions such as CNMP and insomnia and anxiety;
- better integration of health services and increased access to health care providers who specialise in pain management;
- enhanced access to specialist drug treatment services for those for whom this is appropriate;
- ensuring that treatment facilities are available and suitable for patients who do not have a history of injecting drugs use; and
- better management of the hospital to home medication regimes.

There is also a range of changes warranted at the individual practitioner level. These include:

- ensuring that the opioid and benzodiazepine prescription practices reflect the current evidence base concerning the quality use of these medications; and
- the increased use of non-pharmacological treatment approaches to conditions such as CNMP and insomnia and anxiety.

Question 26

What other clinical responses are required?

13.3 Harm reduction measures

The implementation of measures to enhance the quality use of these medications will not prevent all unsanctioned use. The use of these drugs by individuals other than those to whom they were prescribed, or at dosages or by routes of administration that were unintended by prescribers or manufacturers, can be very harmful. These harms include overdose and vascular, organ, limb, or digit damage. It will be important that measures are put in place to minimise these harms. Potential responses that warrant consideration include a range of established harm reduction strategies such as:

- peer education programs concerning the risks associated with using these medications in this way and strategies to avoid harms; and
- ready accessibility of consumables, such as appropriate needles and syringes, winged infusions, syringe driven filters and peer naloxone distribution.

The introduction of measures such as these will ensure that the NPDMS adopts a balanced approach to pharmaceutical drug misuse and balances the three pillars of the National Drug Strategy, namely supply, demand and harm reduction.

13.4 Workforce development issues

There is a range of workforce development issues that warrant consideration as part of the NPDMS. A key aim of the Strategy will be to enhance the quality prescription of the target medications. Key approaches in this regard could include:

- the use of auditing and feedback processes;
- educational outreach;
- educational meetings;
- clinical guidelines; and
- computerised ‘pop up’ prescribing reminders.

Key topics could include such issues as:

- the need for the adoption of universal precautions in the prescription of opioids and benzodiazepines;
- the potentially (but not necessarily) inter-related problems of drug dependence and pain management;
- the availability of, and referral pathways into, specialist pain and drug treatment facilities;
- the current evidence base concerning the use of pharmacotherapy for conditions such as anxiety, insomnia and CNMP and ways to enhance the use of non-pharmacological approaches;
- good practice in managing pain among opioid dependent individuals and those with a history of illicit drug use; and
- responding appropriately to difficult medication-demanding patients.

To achieve this, changes are required in professional education and training but also in mentoring systems, service delivery systems, referral pathways and reimbursement regimes. Also important is the development, dissemination and application of clinical guidelines. Appropriate guidelines need to be developed in the context of the complexity and levels of demands associated with the working environment of the practitioners.

There is a well established literature on measures which are likely to be beneficial in promoting positive changes in clinical practice among health professionals and it will be important that this is taken into consideration in the development of the Strategy.

There is also a need to consider the workforce development needs of other groups responding to pharmaceutical drug misuse problems. Police, for example, are likely to have a range of these needs as they increasingly move into the realm of responding to these problems. Police are likely to have a range of resource needs, such as those which enhance their abilities: to identify different pharmaceutical drugs;[11] to better understand and utilise relevant legislation; and to investigate relevant offences.

Question 27

What other workforce development responses are required?

13.5 Consumer-oriented responses

The first of the five key principles which underpins Australia's National Strategy for the Quality Use of Medicines (NSQUM) is the primacy of consumers. The NSQUM recognises both the central role consumers play in attaining QUM and the wisdom of their experience. Consequently consumers must be involved in the NPDMS at a range of levels. The NPDMS will need to include strategies that:

- address the expectations that consumers have about the efficacy of medicines;
- ensure that consumers understand current best practice in the quality use of medicines and understand their rights and responsibilities in relation to their health care;

[11] One such resource that is currently in existence is the Victorian Drug Investigators' Guide, but this requires updating.

- enhance levels of health literacy among the population;[12]
- enhance and standardise medication labelling; and
- involve awareness raising programs among the general public about the risks of exceeding therapeutic doses of OTC medications.

Question 28

What other consumer-oriented responses are required?

13.6 Technological responses

A key way in which technology could assist in the reduction of pharmaceutical misuse is via a CMMS. There are other possibilities, however.

One such possibility is the development of tamper-resistant technologies which seek to reduce opportunities for the misuse of relevant medications. Broadly there are three approaches to this:

- abuse resistant formulations (ARFs) which use a barrier that make it difficult to tamper with, or extract, the core medication, or renders the tampered tablets unsuitable for injecting or snorting;
- abuse deterrent formulations (ADFs) which deter misuse by pharmacologically modifying the formulation to decrease pleasurable or induce aversive effects; and
- combination ARF and ADF formulations (Webster & Fine, 2010).

These measures can only be expected to reduce, not eliminate the misuse of these substances (Wright et al. 2006). It is also important that these technological approaches do not inadvertently make unsanctioned use more harmful.

A further way in which technology can assist in reducing pharmaceutical misuse is by the implementation of pharmaceutical pedigrees. A pharmaceutical pedigree is an audit trail that follows a drug from the time it is manufactured through the distribution system to a pharmacy and even to the patient level. Radio frequency identification (RFID) can be used in this regard.

It would be of considerable benefit to law enforcement efforts to curb the illicit sale of these medications if this pedigree process were able to be traceable to the tablet or at least blister pack level.

A further important potential contribution of technology relates to the use of prescriptions which are unable to be easily forged or altered.

Question 29

Are there any other potential contributions that technology could make?

[12] Health literacy includes the ability to understand instructions on prescription drug bottles, appointment slips, medical education brochures, prescriber's directions and consent forms, and the ability to negotiate complex health care systems.

13.7 The marketing of medications

The development of the NPDMS provides a good opportunity to consider the marketing of pharmaceuticals and how approaches such as self-regulation contribute to minimising the misuse of pharmaceuticals.

Question 30

To what extent is Australia's current self-regulatory approach to the marketing of pharmaceuticals effective?

14 Summary

The misuse of pharmaceutical drugs in Australia is a problem that needs to be understood and responded to at a variety of levels and involving a range of key stakeholders. There is also a need to balance a range of issues. Foremost among these is the need to reduce the misuse of these drugs without adversely impacting on their clinically appropriate use or in any way stigmatising that use.

A key way of assuring this balance is by undertaking a wide process of consultation in the development of the Strategy. As was discussed in the Foreword this paper is intended to promote discussion and prompt involvement in the consultation process. Readers with an interest in this area are urged to take the opportunity to have input into the Strategy development process by utilising any of the processes outlined in the Foreword.

References

Adhikari, P., & Summerill, A. (2000). *1998 National Drug Strategy Household Survey: Detailed findings. AIHW cat no. PHE 27. Drug Statistics Series No. 6*. Canberra: Australian Institute of Health and Welfare.

AIHW. (2008a). *2007 National Drug Strategy Household Survey. State and territory supplement*. Canberra: Australian Institute of Health and Welfare.

AIHW. (2008b). *2007 National Drug Strategy Household Survey: Detailed findings*. Canberra: Australian Institute of Health and Welfare.

AIHW. (2008c). *2007 National Drug Strategy Household Survey: First results*. Canberra: Australian Institute of Health and Welfare.

AIHW. (2010). *Alcohol and other drug treatment services in Australia 2008-09: report on the National Minimum Data Set*. Canberra: Australian Institute of Health and Welfare.

Bartlett, G., Abrahamowicz, M., Grad, R., Sylvestre, P., & Tamblyn, R. (2009). Association between risk factors for injurious falls and new benzodiazepine prescribing in elderly persons. *BMC Family Practice, 10*(1).

BPS. (2010). *Opioids for persistant pain: Good practice*: The British Pain Society.

CASA. (2005). *Under the counter: The diversion and abuse of controlled prescription drugs in the U.S.*: The National Center on Addiction and Substance Abuse at Columbia University.

CDCP. (2010). *Heat Illness Among High School Athletes - United States, 2005-2009. Morbidity and Mortality Weekly Report. Vol. 59, No. 32.* Atlanta, GA: Centers for Disease Control and Prevention.

Clark, R., Wei, E., & Anderson, P. (1995). Meperidine: Therapeutic use and toxicity. *Journal of Emergency Medicine, 13*(6), 797-802.

Commission on the Social Determinants of Health. (2008). *Closing the gap in a generation: health equity through action on the social determinants of health. Final Report of the Commission on Social Determinants of Health*. Geneva: World Health Organization.

Day, C., Conroy, E., Lowe, J., Kimber, J., Page, K., & Dolan, K. (2005). *Drug use and harms among rural and metropolitan injecting drug users. Technical Report No. 234*. Sydney: National Drug and Alcohol Research Centre. University of New South Wales.

DCPC. (2007). *Inquiry into the misuse/abuse of benzodiazepines and other forms of of pharmaceutical drugs in Victoria: Final report*. Melboune: Parliament of Victoria.

Degenhardt, L., Black, E., Breen, C., Bruno, R., Kinner, S., Roxgurgh, A., et al. (2006). Trends in morphine prescriptions, illicit morphine use and associated harms among regular injecting drug users in Australia. *Drug and Alcohol Review, 25*, 403-412.

Degenhardt, L., Larance, B., Mathers, B., Azim, T., Kamarulzaman, A., Mattick, R., et al. (n.d.). *Benefits and risks of pharmaceutical opioids: Essential treatment and diverted medication.* Sydney: National Drug and Alcohol Research Centre.

Department of Health and Ageing. (2008). Expenditure and prescriptions twelve months to 30 June 2007. Retrieved 11 March 2009, from http://www.health.gov.au/internet/main/publishing.nsf/Content/A58720844CBFCB47CA257218000D91C7/$File/pbpa%20annual%20report%202007.pdf

Dobbin, M. (2008). *Non-prescription (over-the-counter) codeine-containing analgesic misuse and harm*. Melbourne: Mental Health and Drugs Division, Department of Human Services.

Dobbin, M. (2009). *Misuse of pharmaceutical drugs in Australia*. Victoria: Department of Health.

Dobbin, M. (2010). Pharmaceutical drugs:maintaining appropriate use while preventing diversion. Presentation given to the United nations Office on Drugs and Crime technical consultation in Vienna from 22 to 24 June 2010, available at . http://www.unodc.org/unodc/en/drug-prevention-and-treatment/non-medical-use-prescription-drugs.html.

Dobbin, M. (2011). *Misuse of pharmaceutical drugs in Australia*. Victoria: Department of Health.

European Monitoring Centre for Drugs and Drug Addiction. (2010). *The state of the drugs problem in Europe Annual Report 2010*. Luxembourg: European Monitoring Centre for Drugs and Drug Addiction.

Fischer, B., Bibby, M., & Bouchard, M. (2010). The global diversion of pharmaceutical drugs Non-medical use and diversion of psychotropic prescription drugs in North America: A review of sourcing routes and control measures. *Addiction, 105*(12), 2062-2070.

Fischer, B., & Rehm, J. (2007). Illicit opioid use in the 21st century: witnessing a paradigm shift? *Addiction, 102*, 499-501.

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, 9*(3), 159-167.

Fry, C., Smith, B., Bruno, R., O'Keefe, B., & Miller, P. (2007). *Benzodiazepine and pharmaceutical opioid misuse and their relationship to crime: An examination of illicit prescription drug markets in Melbourne, Hobart and Darwin*: Commonwealth of Australia.

Gaffney, A., Jones, W., Sweeny, J., & Payne, J. (2010). *Drug use monitoring in Australia: 2008 annual report on drug use among police detainees*. ACT: Australian Government Australian Institute of Criminology.

Gourlay, D. L., Heit, H. A., & Almahrezi, A. (2005). Universal precautions in pain management: A rational approach to the treatment of chronic pain. *Pain Medicine, 6*(2), 107-112.

Hotham, E., Roche, A., Skinner, N., & Dollman, W. (2005). The general practitioner pharmacotherapy prescribing workforce: examining sustainability from a systems perspective, *Drug and Alcohol Review*, 24:393-400

INCB. (2006). *Report on the International Narcotics Control Board for 2005*. Vienna: International Narcotics Control Board.

INCB. (2008). *Report of the International Narcotics Control Board for 2007*. Vienna: International Narcotics Control Board.

INCB. (2010). *Report on the International Narcotics Control Board for 2010*. Vienna: United Nations, International Narcotics Control Board.

Kinjo, M., Setoguchi, S., Schneeweiss, S., & Solomon, D. H. (2005). Bone mineral density in subjects using central nervous system-active medications. *The American Journal of Medicine, 18*, 1414.e1417-1414.e1412.

Mattick, R. P., Breen, C., Kimber, J., & Davoli, M. (2009). *Methadone maintenance therapy versus no opioid therapy for oriod depences*. Cochrane Database of Systematic Reviews Issue 3. Art. No.: CD002209.

Medicare Australia. (2011). Prescription shopping program. Retrieved 5 February 2011, from http://www.medicareaustralia.gov.au/provider/pbs/prescription-shopping/index.jsp#N1002A

Monheit, B. (2010). Prescription drug misuse. *Australian Family Physician 39*(8), 540-546.

MSIC. (2010). *Face up*. NSW: Medically Supervised Injecting Centre Uniting *Care*.

NCHECR. (2010). *Australian NSP survey national data report 2005 - 2009: Prevalence of HIV, HCV and injecting and sexual behaviour among IDUs at needle and syringe programs*. Sydney: National Centre in HIV Epidemiology and Clinical Research, The University of New South Wales.

National Health and Medical Research Council. (2000). *How to Use the Evidence: Assessment and Application of Scientific Evidence.* Canberra: Commonwealth of Australia.

Nicholas, R. (2002). *The diversion of pharmaceutical drugs onto the illicit market*: Australasian Centre for Police Research.

Nicholas, R. (2010). *An environmental scan on alcohol and other drug issues facing law enforcement in Australia 2010*. Hobart: National Drug Law Enforcement Research Fund.

Nielsen, S., & Barratt, M. J. (2009). Prescription drug misuse: Is technology friend or foe? *Drug and Alcohol Review, 28*, 81-86.

Nielsen, S., Bruno, R., Carruthers, S., Fischer, J., Lintzeris, N., & Stoove, M. (2008). *Investigation of pharmaceutical misuse amongst drug treatment clinics: Final report 2008*: Turning Point Alcohol & Drug Centre.

Noble, M., Treadwell, J. R., Tregear, S. J., Coates, V. H., Wiffen, P. J., Akafomo, C., et al. (2010). *Long-term opioid management for chronic noncancer pain (Review)*. Cochrane Database of Systematic Reviews 2010, Issue 1. Art. No.: CD006605.

Passik, S. D., & Kirsh, K. L. (2008). The interface between pain and drug abuse and the evolution of strategies to optimize pain management while minimizing drug abuse. *American Psychological Associaition, 16*(5), 400-404.

Professional Services Review. Report to the Professions 2008-2009. Retrieved from: http://www.psr.gov.au/docs/publications/html08-09/the-psr-scheme.html

Paulozzi, L. J. (2006). Opioid analgesic involvement in drug abuse deaths in American metropolitan areas. *American Journal of Public Health, 96*(10), 1755-1757.

RACP. (2009). *Prescription opioid policy: Improving management of chronic non-malignant pain and prevention of problems associated with prescription opioid use*: The Royal Australasian College of Physicians.

Rintoul, A. C., Dobbin, M., Drummer, O. H., & Ozanne-Smith, J. (2010). Increasing deaths involving oxycodone, Victoria, Australia, 2000-09. *Injury Prevention, Advanced online publication*.

Ritter, A., & Chalmers, J. (2009). *Polygon: The many sides of to the Australian opioid pharmacotherapy maintenance system, ANCD research paper no. 18*. Canberra: Australian National Council on Drugs.

Rodwell, L., Ringland, C., & Bradford, D. (2010). *What do police data tell us about criminal methods of obtaining prescription drugs? Crime and Justice Bulletin No. 139*. Sydney: NSW Bureau of Crime Statistics and Research.

SAMHSA. (2008a). *Drug Abuse Warning Network, 2006: National estimates of drug-related emergency department visits. DAWN Series D-30, DHHS Publication No. (SMA) 08-4339*. Rockville, MD: SAMHSA, Office of Applied Studies.

SAMHSA. (2008b). *The NSDUH report: Nonmedical use of pain relievers in substate regions: 2004 to 2006*. Rockville, MD: Substance Abuse and Mental Health Services Administration.

Sproule, B., Brands, B., Li, S., & Catz-Biro, L. (2009). Changing patterns in opioid addiction: Characterizing users of oxycodone and other opioids. *Canadian Family Physician, 55*, 68-73.

St George, B. N., Emmanuel, J. R., & Middleton, K. L. (2004). Overseas-based online pharmacies: A source of supply for illicit drug users? *The Medical Journal of Australia, 180*, 118-119.

Stafford, J., & Burns, L. (2010). *Australian drug trends 2009: findings from the Illicit Drug reporting System (IDRS)*: National Drug and Alcohol Research Centre.

The Marmot Review. (2010). *Fair society, healthy lives: Strategic review of health inequalities in England post-2010*. Retrieved from http://www.marmotreview.org/AssetLibrary/pdfs/Reports/FairSocietyHealthyLives.pdf.

Thomson, N., Harney, A., & Lee, N. (2008). *Benzodiazepine treatment capacity building project: Final report*. Victoria: Turning Point Alcohol and Drug Centre.

UNODC. (2010). *2010 World Drug Report*. Vienna: United Nations Office on Drugs and Crime.

Webster, L. R., & Fine, P. G. (2010). Approaches to improve pain relief while minimizing opioid abuse liability. *The Journal of Pain, 11*(7), 602-611.

Western Australian Psychotropic Drugs Committee. (2008). *Anxiety disorders: Drug treatment guidelines*. Perth: The Western Australian Therapeutics Advisory Group.

Woods, J., Gerostamoulos, D., & Drummer, O. (2007). *Heroin Deaths in Victoria 2006*. Melbourne: Victorian Institute of Forensic Medicine, Department of Forensic Medicine, Monash University.

Wright, C., Kramer, E. D., Zalman, M., Smith, M. Y., & Haddox, J. D. (2006). Risk identification, risk assessment, and risk management of abusable drug formulations. *Drug and Alcohol Dependence, 83S*, S68-S76.