

**NATIONAL PHARMACEUTICAL
DRUG MISUSE
FRAMEWORK FOR ACTION
(2012-2015)**

A MATTER OF BALANCE

Table of Contents

FOREWORD	i
ACKNOWLEDGEMENTS	ii
PART ONE: BACKGROUND	1
Introduction.....	1
Why Australia needs a National Pharmaceutical Drug Misuse Framework for Action	2
The spectrum of pharmaceutical drug misuse problems	3
The quality use of medicines	4
The need for balance.....	5
Workforce development.....	5
The Framework development process.....	6
The Framework context.....	7
Stakeholders	7
Next steps	8
PART TWO: THE FRAMEWORK.....	10
Priority Areas.....	10
PART THREE: THE RATIONALE FOR ACTION AREAS	15
1. Coordinated medication management system.....	15
2. Supporting prescribers	20
3. Supporting pharmacists and other health professionals	25
4. Regulation and monitoring.....	28
5. Structural factors	34
6. Health information and other consumer responses.....	41
7. Treatment and harm reduction	44
8. Technological responses.....	47
9. Data, research and evaluation.....	49
APPENDIX I: THE NEED FOR A FRAMEWORK	51
Prescription and non-prescription opioids	51
Benzodiazepines	54
Are medications the best options?	56
Law enforcement-related harms	58
Systemic factors impacting on the quality use of medications and opportunities for misuse ..60	
Knowledge gaps.....	62
APPENDIX II: Links to other strategies	63
APPENDIX III: Abbreviations	76

APPENDIX IV: Glossary of Medicines.....	77
APPENDIX V: Glossary of Terms.....	78
References	80

FOREWORD

Within the context of the National Drug Strategy 2010-2015, the National Pharmaceutical Drug Misuse Framework for Action identifies national priorities and provides a guide for actions to minimise the harms to individuals, families and communities from pharmaceutical drug misuse.

The goals of the Framework are:

- To reduce the misuse of pharmaceutical drugs and associated harms in Australia; and
- To enhance the quality use of pharmaceutical drugs without stigmatisation or limiting their accessibility for therapeutic use.

The Framework provides a holistic approach, in keeping with the complex range of factors that contribute to pharmaceutical drug misuse. The priority areas identified for action were informed by an extensive national consultation process involving written submissions, consultation workshops, a review of the literature, discussions with key experts and guidance from an Expert Reference Group and a Project Steering Committee.

The nine priority areas are:

- Coordinated medication management system;
- Supporting prescribers;
- Supporting pharmacists and other health professionals;
- Regulation and monitoring;
- Structural factors;
- Health information and other consumer responses;
- Treatment and harm reduction;
- Technological responses; and
- Data, research and evaluation.

Responsibility for implementing the actions outlined in the National Pharmaceutical Drug Misuse Framework for Action will be shared by all governments, recognising that jurisdictions face different challenges and will undertake actions in line with their own priorities, timing and resources.

ACKNOWLEDGEMENTS

A range of individuals assisted with the preparation of this Framework. These included:

The Project Management Committee for the National Pharmaceutical Drug Misuse Framework for Action (NPDMFA) from the Victoria Department of Health and NSW Police Force:

- Mr Pier DeCarlo
- Dr Malcolm Dobbin
- Ms Jenny Holmes
- Ms Irene Tomaszewski
- Ms Pat Ward.

Members of the NPDMFA Project Consortium Group:

- Professor Ann Roche (NCETA, Flinders University)
- Mr Roger Nicholas (NCETA, Flinders University)
- Associate Professor Nicole Lee (NCETA, Flinders University)
- Mr Allan Trifonoff (NCETA, Flinders University)
- Ms Carol Bennett (Consumer Health Forum of Australia)
- Mr Colin Brown (SA Health)
- Professor James Dunbar (Flinders University)
- Professor Jason White (University of SA)
- Associate Professor Robert Ali (University of Adelaide)
- Professor Michael Kidd (Flinders University)
- Dr Penny Briscoe (Royal Adelaide Hospital)
- Ms Tania Steenson (NCETA, Flinders University)
- Ms Anne Lawrance (NSW Health) – Technical adviser

Members of the NPDMFA Project Steering Committee:

- Mr Michael Gorman (Victoria Police)
- Dr Michael Pitt (Australian Government Department of Health and Ageing)
- Mr Michael Bolt (Australian Government Department of Health and Ageing)
- Mr Bruce Battye (NSW Health)
- Ms Fiona Wynn (NSW Mental Health and Drugs and Alcohol Office)
- Superintendent Patrick Paroz (NSW Police)
- Ms Sarah Gobbert (NT Health)
- Dr Sue Ballantyne (Queensland Health)
- Det Sergeant Mick Ackery (Queensland Police)
- Sergeant Adam Frost (Queensland Police)
- Ms Simone Cormack (SA Health)
- Mr Steve Morris (SA Health)
- Ms Maryann Elias (SA Health)
- Ms Sylvia Engels (Tasmania Department of Health and Human Services)
- Dr Adrian Reynolds (Tasmania Department of Health and Human Services)
- Ms Anna Gelavis (WA Health)
- Superintendent James Migro (Western Australia Police Service)

- Ms Jacqueline Durand (Australian and New Zealand Policing Advisory Agency)
- Mr Kim Bessell (Australian Health Ministers Advisory Council)
- Dr Allan Quigley (Australian Health Ministers Advisory Council)

Members of the NPDMFA Project Expert Reference Group:

- Associate Professor Yvonne Bonomo (RACP Australasian Chapter of Addiction Medicine)
- Professor Jon Currie (RACP Australasian Chapter of Addiction Medicine)
- Dr Penny Briscoe (Faculty of Pain Medicine, ANZ College of Anaesthetists)
- Dr Michael Nolan (Australian General Practice Network)
- Professor Dan Lubman (Royal ANZ College of Psychiatrists)
- Dr Lynn Weekes (National Prescribing Service)
- Mr Irvine Newton (Pharmaceutical Society of Australia)
- Ms Kate Mackie (Society of Hospital Pharmacists of Australia)
- Mr Stephen Marty (Pharmacy Board of Australia)
- Professor Jason White (University of SA)
- Detective Superintendent Nick Bingham (NSW Police)
- Superintendent Charlie Carver (WA Police Service)
- Ms Christine Vincent (Victoria Police)
- Dr Suzi Nielsen (Alcohol and other Drugs Council of Australia Pharmaceutical Drug Working Group)
- Ms Ros Burnett (Drug and Alcohol Nurses Association)
- Professor Margaret Hamilton (Australian National Council on Drugs)
- Ms Mary Sharpe (Tasmania Department of Health and Human Services)
- Mr Matthew McCrone (Department of Health, Victoria)
- Mr Kim Bessell (Australian Government Department of Health and Ageing)
- Mr Sam Liebelt (Australian Injecting and Illicit Drug Users League)
- Ms Coralie Wales (Chronic Pain Australia)
- Associate Professor Nicholas Lintzeris (Drug and Alcohol Services, South Eastern Sydney and Illawarra Area Health Service)

Australia's National Pharmaceutical Drug Misuse Framework for Action

Goals: To reduce the misuse of pharmaceutical drugs and associated harms in Australia.

To enhance the quality use of pharmaceutical drugs without stigmatisation or limiting their accessibility for therapeutic use.

Focus: The Framework is underpinned by a focus on quality use of prescription and non-prescription opioids and benzodiazepines (including the use of evidence-based alternative therapies).

1. Coordinated medication management system

A coordinated medication management system is an on line, real time tool that provides information on patients' relevant medication usage for prescribers, pharmacists and regulators. It is important that such a system be linked to the regulatory and monitoring approaches outlined in Priority Area 4.

- 1.1 Progress implementation of the nationally-based and jurisdictionally consistent Electronic Recording and Controlled Drugs (ERBCD) system which enables prescribers, dispensers and regulators to have real time online access to information concerning patients' access to prescription opioids and other Schedule 8 medicines.
- 1.2 Consider future enhancements to meet the characteristics of a comprehensive coordinated medication management system.
- 1.3 Where necessary, enhance the required regulatory infrastructure to respond to ERBCD system-generated data.
- 1.4 Coordinate national education about the ERBCD system for health and welfare professionals and the broader community.

5. Structural factors

This section addresses a range of issues related to access to services, medication management and prescriber remuneration which may contribute to pharmaceutical drug misuse.

- 5.1 Explore opportunities to improve access to treatments and services.
 - 5.1.1 Explore options to improve access to multidisciplinary and non-pharmacological treatments for conditions such as chronic non-malignant pain, anxiety and insomnia.
 - 5.1.2 Explore options to improve access to comprehensive, multidisciplinary, specialist pain facilities, particularly in the public sector.
 - 5.1.3 Explore options to improve access to comprehensive, multidisciplinary specialist sleep and mental health facilities, particularly in the public sector.
 - 5.1.4 Explore options to improve the access that prescribers, pharmacists and patients have to specialist alcohol and other drug treatment services and expertise.
 - 5.1.5 Explore opportunities to improve access to non-opioid adjuvant medications for pain conditions by encouraging sponsors to make submissions to the Pharmaceutical Benefits Advisory Committee for them to be listed on the Pharmaceutical Benefits Scheme.
 - 5.1.6 Explore opportunities to reduce current obstacles to opioid substitution therapy programs in Australia.
- 5.2 Explore opportunities to enhance liaison in transitional medication management between hospitals and community settings.
- 5.3 Where possible, enhance the range of medication pack sizes and/or dispensing options for Pharmaceutical Benefits Scheme medications.
- 5.4 Promote utilisation by prescribers of Medicare Benefits Schedule items which remunerate and target medication review and/or non-pharmacological management of conditions such as pain and mental illness.

2. Supporting prescribers

This area focuses on a range of strategies that enhance prescribing practice to minimise intentional and unintentional misuse. This includes the development of prescribing guidelines and workforce development measures.

- 2.1 Develop and/or re-iterate national guidelines for the (non-pharmacological and pharmacological) treatment of conditions commonly implicated in the problematic use of these pharmaceuticals including:
 - Pain (acute, chronic non-malignant and cancer);
 - Mental health problems (e.g. anxiety);
 - Sleep disorders; and
 - Alcohol and other drug use problems (including pharmacotherapy).
- 2.2 Explore options to enhance peer review mechanisms, practice enhancement approaches and disciplinary measures for prescribers who consistently and inappropriately prescribe outside the boundaries of the proposed guidelines.
- 2.3 Enhance ongoing medical, postgraduate and in-service education programs for health and human services workforce about the quality management of problems such as pain, mental health problems, sleep disorders and alcohol and other drug problems.
- 2.4 Identify opportunities to better support prescribers who feel pressured by patients to provide medications inappropriately.

6. Health information and other consumer responses

This section addresses a range of health literacy issues including problems related to the acceptability of non-pharmacological treatments, the accessibility of information, medication labelling and the protection of patients' rights.

- 6.1 Widen the acceptability of non-drug and non-opioid, non-benzodiazepine treatments for physical and psychological problems.
- 6.2 Enhance the accessibility of information available to consumers regarding the potential harms associated with opioids and benzodiazepines.
- 6.3 Further standardise the labelling of medicines in Australia.
- 6.4 Promote the availability of review and appeal processes for patients and their prescribers who believe that access to target medications has been unfairly denied by enhanced monitoring and regulation.

8. Technological responses

This area seeks to implement measures such as tamper resistant medications, pharmaceutical tracking measures and electronic prescribing to reduce pharmaceutical drug misuse.

- 8.1 Promote the use of tamper-resistant technologies for target medications.
- 8.2 Consider the feasibility of implementing pharmaceutical pedigrees.
- 8.3 Enhance the use of electronic prescriptions to minimise the risk of dispensing errors and fraudulent alteration of prescriptions.

3. Supporting pharmacists and other health professionals

This includes actions to enhance the role of pharmacists in medication management as well as a range of practice enhancement measures for this group. It also highlights the need for other health professionals to be more aware of and involved in the appropriate treatment options for conditions such as pain, anxiety and sleep disorders.

- 3.1 Explore opportunities to enhance the contribution that pharmacists can make to the care plans of patients.
- 3.2 Review and, where necessary, enhance protocols for pharmacists concerning acceptable practice in the dispensing of these medications.
- 3.3 Investigate options to improve access to undergraduate and in-service professional development programs for pharmacists to better utilise their professional abilities to enhance the quality use of these medications.
- 3.4 Investigate options to establish or enhance peer review mechanisms and practice enhancement measures for pharmacists who dispense outside of protocol boundaries.
- 3.5 Enhance the current pharmacy staged supply arrangements.
- 3.6 Enhance the quality use of medicines in residential aged care facilities.
- 3.7 Enhance the awareness of a range of health and welfare professionals regarding effective treatments for:
 - Pain (acute, chronic non-malignant and cancer);
 - Mental health problems (e.g. anxiety);
 - Sleep disorders; and
 - Alcohol and other drug use problems (including pharmacotherapy).

7. Treatment and harm reduction

This priority area focuses on the treatment needs of people with pharmaceutical drug misuse problems and the access that Australians have to the resources they need to reduce the harms associated with pharmaceutical drug misuse.

- 7.1 If necessary, re-orientate existing services or develop new programs to address the needs of the clients experiencing difficulties with problematic pharmaceutical use including (but not limited to) those who do not, have a history of illicit drug use.
- 7.2 Enhance the capacity of treatment services to meet the needs of ageing populations who have had longer term exposure to pharmaceutical and non-pharmaceutical opioids.
- 7.3 Enhance access to options available for police and courts to divert offenders involved in the problematic use of these medicines away from the criminal justice system.
- 7.4 Ensure that Australia's needle and syringe programs have the ability to respond to the trend towards the misuse of pharmaceutical medications by injection.
- 7.5 Better disseminate information concerning the potential harms and evidence-informed harm reduction measures to those involved, or potentially involved in the problematic use of these pharmaceuticals.
- 7.6 Explore opportunities to expand needle and syringe programs into rural areas to a larger extent than is currently the case.

4. Regulation and Monitoring

This includes a range of enhancements to, and standardisation of, the ways medications are regulated and monitored and the ways in which data about pharmaceutical drugs are shared. The approaches outlined in this Priority Area should have close links to the coordinated medication management system (Priority Area 1).

- 4.1 Evaluate the extent to which different jurisdictional regulatory models impact on the misuse of these drugs and identify standardisation benchmarks for good practice.
- 4.2 Provide this Framework to the delegate of the Secretary of the Department of Health and Ageing for consideration in determining the need for a review of scheduling of opioids and benzodiazepines.
- 4.3 Explore options to enhance the information sharing capacities of law enforcement and health agencies to reduce opportunities for theft, diversion, trafficking and fraud in pharmaceutical drugs.
- 4.4 Monitor and respond to emerging trends in local and international internet pharmacies.
- 4.5 Consider the deliberations of the Working Group on the Promotion of Therapeutic Products regarding strengthening the self-regulatory framework governing the relationship between health care professionals and therapeutic goods companies.
- 4.6 Assess the feasibility of removing opioid and benzodiazepine medications from advertising in pharmacy price lists.
- 4.7 Encourage the Pharmaceutical Benefits Advisory Committee and the Therapeutic Goods Administration to increase the emphasis placed on potential harms associated with pharmaceutical drug misuse in their decision making processes.
- 4.8 Explore opportunities to ensure that the enhanced monitoring and regulation of medications intended for human consumption does not enhance diversion from veterinary supplies.

9. Data, research, and evaluation

This priority area contains strategies to enhance our understanding of the extent and nature of pharmaceutical drug misuse in Australia and appropriate responses.

- 9.1 Enhance and better co-ordinate pharmaceutical-related data collection and sharing processes to provide a more holistic picture of patterns of the prescription and utilisation as well as profiles and levels of harm.
- 9.2 Conduct a range of specific research activities to focus on areas that could better inform public policy in this area.
- 9.3 Develop an action research based methodology to assess the intended and unintended outcomes of the implementation of this Framework.

Workforce Development Actions appear in Green

PART ONE: BACKGROUND

Introduction

Pharmaceutical drugs provide a broad range of benefits to Australians. The myriad of medications available enhance our quality of life and many are widely and appropriately used in the community. The fact that some medicines are also subject to misuse, or poor quality use, in no way detracts from these benefits. In addition, Australia is fortunate that its Pharmaceutical Benefits Scheme (PBS) makes many medicines readily accessible by world standards.

Nevertheless, the misuse and poor quality use of these medications is an issue of increasing concern in some circumstances. This trend involves a wide range of pharmaceutical drugs, but opioids (both prescription and non-prescription) and benzodiazepines are of particular concern.

Australia has experienced a substantial increase in opioid supply in recent years (Dobbin, 2011) with a range of associated harms including:

- pharmaceutical drug-related emergency department presentations and fatal and non-fatal overdoses;
- the risk of blood borne diseases and the specific harms associated with injection and inhalation of oral pharmaceuticals;
- individuals seeking treatment for prescription opioid or benzodiazepine dependence;
- levels of trafficking in, and police seizures of, pharmaceutical drugs; and
- robbery, theft, identity fraud, extortion and the manufacture of illicit drugs.

This increase in harms reflects patterns seen in other countries such as the United States and Canada.¹

In response, the Ministerial Council on Drug Strategy (MCDS) requested that a National Pharmaceutical Drug Misuse Framework for Action be developed, funded through the Cost Shared Funding Model. The Intergovernmental Committee on Drugs (IGCD) has established a Standing Committee on Pharmaceutical Drug Misuse to oversee the development and implementation of the Framework.

The MCDS requested that the Framework focus on pharmaceutical opioids (including over the counter codeine-containing analgesics) and benzodiazepines and use them as framework development 'prototypes'. The Framework also has relevance to other prescription drugs including psycho-stimulants, anti-depressants, anti-psychotics and performance and image

¹ For example the misuse of and trafficking in prescription drugs has now exceeded that of illicit drugs in some countries and these drugs have become a drug of first choice in many cases and are not being used as a substitute for illicit drugs (International Narcotics Control Board, 2010). In addition between 1999 and 2007 in the United States, poisoning deaths involving opioid analgesics more than tripled, from 4,041 to 14,459 (Centers for Disease Control and Prevention, 2010). Likewise emergency department visits in that country involving the misuse or abuse of pharmaceuticals increased from 627,291 visits in 2004 to 1,244,679 visits in 2009, an increase of 98.4% (Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, 2010).

enhancing drugs and over the counter drugs including some cough suppressants and anti-histamines.

The problems associated with the misuse and poor quality use of these pharmaceutical drugs have complex contributory factors and require multi-layered responses. For instance:

- A range of structural issues, including aspects of Australia's health and welfare systems may exacerbate problems.
- A need exists for practice enhancement among a range of health professionals, in particular, prescribers and pharmacists, to facilitate improved quality use of medications.
- There is also a need to enhance health literacy levels among health care consumers to enable them to make better use of these medicines.
- It is important to enhance the capacity of law enforcement agencies to respond to the range of crimes associated with pharmaceutical drug misuse.

Also, Australia's population is ageing. As this occurs, the prevalence of painful conditions will increase. The prevalence of psychological disorders, such as anxiety, also increases with advancing years, peaking in middle age. As a result, the population level demand for medications such as opioids and benzodiazepines could be expected to increase.

The Framework adopts a holistic approach to addressing these problems which is in keeping with the complex range of factors that contribute to pharmaceutical drug misuse. The Framework is consistent with Australia's National Strategy for the Quality Use of Medicines. Nine priority areas for action are identified. These were informed by an extensive consultation process involving written submissions, consultation workshops, a review of the literature, discussions with key experts and guidance from an Expert Reference Group and a Project Steering Committee.

Why Australia needs a National Pharmaceutical Drug Misuse Framework for Action

Over the past two decades Australia, as with some other developed countries, has seen a significant increase in the prescribing of certain opioid medications, particularly in slow release formulations. Between 1991 and 2010, for example, the Australian population increased by 29% but there was an increase of 228% by weight in the pharmaceutical opioid base supply to Australia. Over the past decade the overall level of benzodiazepine prescribing in Australia has increased somewhat but a significant change has occurred in the profile of benzodiazepines being prescribed. In particular the prescribing of the benzodiazepine alprazolam has increased by one third.

The increase in supply of many of these medications is not necessarily problematic of itself. Unfortunately this has also been associated with an increase in a range of harms in Australia and internationally. For example in Australia:

- pharmaceutical opioid-related poisoning hospitalisations now exceed those associated with heroin use;
- deaths associated with pharmaceutical opioid misuse are increasing;
- the injection of oral medicines is becoming increasingly prevalent which poses risks for the spread of blood borne diseases;
- inappropriate prescribing is likely to be leading to sub-optimal treatment outcomes for a range of conditions, such as persistent pain, anxiety and sleep disorders;
- an illicit trade in pharmaceutical drugs has emerged in some jurisdictions;
- crimes are committed to obtain pharmaceutical drugs or while under their influence; and
- a range of adverse economic impacts are occurring.

In particular, the problematic use of the benzodiazepine alprazolam is associated with a disproportionately large level of harms. These include overdose deaths, seizures and rage responses among users, as well as traffic accidents and crime-related harms.

Many of these harms have reached very serious proportions in other countries such as the United States and Canada. A timely response to pharmaceutical drug misuse problems will enable Australia to intervene in these problems before they reach this extent.

These harms are outlined more fully in Appendix 1.

The spectrum of pharmaceutical drug misuse problems

For many consumers, pharmaceutical drugs provide an effective and appropriate treatment for a range of conditions. However, various problematic patterns of pharmaceutical drug consumption can occur. Individuals may take medications as prescribed but in response to inappropriate prescribing practices. Australia is likely to have a large but relatively hidden population of such individuals who unintentionally misuse these medications and who have developed an iatrogenic dependence² (Royal Australasian College of Physicians, RACP, 2009). So too for some, the benefits derived from the use of medicines are no longer optimal and alternative more effective treatment options exist.

Some people may also be using medications in ways that are not consistent with their prescriptions and some may be obtaining and using large quantities of medications by visiting a range of prescribers and dispensers (prescription shopping). Others may be accumulating and on-selling medications for profit or be involved in thefts or fraud to obtain these drugs.

Consequently, the misuse/poor quality use of medicines occurs on a spectrum ranging from those who unintentionally misuse these medications in response to inappropriate prescribing practices, through to those who intentionally obtain and misuse medications for their non-therapeutic effects and/or for financial gain.

² Iatrogenic dependence is dependence stemming from medical treatment or advice.

Problems may also emerge with over the counter codeine-containing medications, if they are taken in quantities that lead to codeine dependence or health problems associated with consuming large doses of ibuprofen or paracetamol which can also be found in analgesics containing codeine.

This spectrum of problems can result in harms that require different responses. Some responses are required from the health sector. Others are required from the law enforcement sector where illegality is involved. Trafficking in illicit pharmaceutical drugs is a major emerging problem 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 criminal entrepreneurs to enter the illicit pharmaceuticals market.

The quality use of medicines

The primary focus of the Framework is on reducing the inappropriate use of pharmaceuticals through a range of measures including better informed prescribing and reducing opportunities for misuse. The Framework forms part of a suite of measures designed to enhance the quality use of medicines. Consistent with Australia's National Strategy for the Quality Use of Medicines, the National Pharmaceutical Drug Misuse Framework for Action seeks to improve the quality use of medicines by involving healthcare consumers, practitioners, providers and educators, the medicines industry and governments.

Like the National Pharmaceutical Drug Misuse Framework for Action, the goal of the National Strategy for the Quality Use of Medicines is to make the best possible use of medicines to improve health outcomes for all Australians. This recognises that many people maintain their health without using medicines, while for others, medicines play an important role in maintaining health, preventing illness and curing disease (Commonwealth of Australia, 2002).

The National Medicines Policy is also consistent with the National Pharmaceutical Drug Misuse Framework for Action, in that it seeks to:

- ensure timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- ensure that medicines meet appropriate standards of quality, safety and efficacy;
- enhance the quality use of medicine; and
- maintain a responsible and viable medicines industry (Commonwealth of Australia, 1999).

As is evident, there is a high degree of consistency between the outcomes sought by the National Pharmaceutical Drug Misuse Framework for Action, the National Strategy for the Quality Use of Medicines and the National Medicines Policy.

All partners to the National Medicines Policy have made significant contributions to the quality use of medicines across Australia over the last 15 years. These have delivered significant

benefits to Australians who use medicines, as well as those who have their conditions treated without the use of medicines. Some of these contributions have been directed toward opioids and benzodiazepines.³

Despite these efforts, it is evident that further quality use of medicines activity is required to complement and build on existing work in relation to opioids and benzodiazepines.

The need for balance

A key theme in the Framework is achieving a balance among diverse interests and ensuring that no Australians are disadvantaged or stigmatised. There is also a need to ensure continued medical access to these medications and to maximise their appropriate use, while minimising opportunities for misuse. There is a need to ensure that the clinically appropriate supply of these medications is maintained. It is also important that the Framework empowers prescribers and pharmacists, enhances the information at their disposal and informs their decision-making.

Workforce development

The Framework includes a range of workforce development initiatives for health, welfare, law enforcement and other workers in Australia across the priority areas. These include the development and implementation of clinical guidelines, enhancing undergraduate, postgraduate and inservice education programs and implementing strategies to better support clinicians and other groups responding to pharmaceutical drug misuse problems. It is important that these workforce development approaches are based on evidence concerning effective ways of changing practice. The workforce development aspects of the Framework are highlighted in green in the outline provided at the beginning of the Framework document (see page iv).

³ On 30 January 2011, for example, the Government-funded National Prescribing Service (NPS) launched a mass media campaign that focuses on the reasons why Australians need to pay more attention to their medicines. The *Be Medicinewise* campaign encourages Australians to start asking “why” before taking a medicine – and to know where to find the correct answers. The *Managing Pain* component of this campaign commenced in late February 2011.

In addition, the NPS website (www.nps.org.au) provides consumers and health professionals access to:

- general information on managing pain using interactive rotating images of medication packaging to identify critical information particularly concerning the active ingredients of over the counter medicines;
- analgesic dosing information for children such as choosing pain relievers, determining and measuring the correct dosages, including a video on child dosing and weighing children;
- information (including three videos) on managing acute lower back pain, such as the most appropriate medicines for this condition and the fact that scans are unlikely to assist in its management; and
- general information, booklets, support and tools on a range of medicine related topics.

In addition to this campaign, the NPS is also conducting an education program for health professionals focusing on the use of opioids in chronic pain. As a part of this education, the NPS has developed a number of health professional publications (such as Prescribing Practice Review and NPS News) and health professional activities (such as case studies and clinical audits), as well as consumer resources (such as patient factsheets and toolkits).

The Framework development process

Development of this Framework was overseen by a Steering Committee with representation from the Intergovernmental Committee on Drugs and the Australian Health Ministers' Advisory Council and guided by an Expert Reference Group.

The Framework was developed following extensive consultation with government, consumer, industry and professional groups. Consultation forums were held in all jurisdictions and meetings were held with key experts in this area, including representatives of the pharmaceutical industry. As part of the consultation process the project team also sought written submissions from interested parties. Forty six written submissions were received and were subsequently analysed and incorporated into the Framework.

An extensive literature review was undertaken and the emergent discussion paper formed the basis of the national consultation process. The literature review and discussion paper are available here:

http://nceta.flinders.edu.au/nceta/publications-and-presentations/nceta_publications/

A high degree of consensus was identified about the extent and nature of pharmaceutical drug misuse problems in Australia and the ways in which they should be addressed. There were also areas of tension, particularly in relation to the resourcing implications of parts of the Framework.

A wide range of factors contribute to concerns about existing patterns of opioid and benzodiazepine use and this is reflected in the Framework. However, not all contributory factors can be fully described in the Framework. As such, this document should be read in conjunction with the discussion paper in order to gain a more comprehensive and contextual insight into the development of the Framework. In addition, some aspects of the Framework will be able to be implemented in the short-term while others will take longer.

The Framework context

This Framework was informed by, and complements, a range of existing strategies and areas of effort. These include:

Strategies

- The National Drug Strategy (2010-2015)
- The National Strategy for the Quality use of Medicines (2002) and the broader National Medicines Policy (1999)
- The National Health Reform Agenda
- The National E-Health Strategy (2008)
- The National Pain Strategy (2010)
- The National Mental Health Policy (2008)
- The National Needle and Syringe Programs Strategic Framework (2010-14)

Existing areas of effort

- The Australian Commission on Safety and Quality in Health Care
- The National Prescribing Service
- Existing Medicare Australia compliance activities, and
- Existing clinical guidelines for the prescription of opioids and benzodiazepines.

Please see Appendix II for an outline of the links between this Framework and other relevant strategies.

Stakeholders

This Framework is relevant to all Australians, particularly health and welfare professionals including prescribers, pharmacists, psychologists, physiotherapists, nurses, counsellors, drug treatment agencies and needle and syringe providers. Providers of undergraduate and post graduate education for these professionals, their respective organisations and registration boards are also important stakeholders.

Government-funded stakeholders include regulators of drugs and poisons, Medicare locals, law enforcement agencies, a range of other Australian government-funded agencies and peak pharmaceutical advisory bodies. Consumers are also a key audience of the Framework, particularly those suffering from chronic pain, alcohol and other drug problems, mental health problems, social disadvantage and their respective support and advocacy groups.

Also important is the prescription and non-prescription pharmaceutical industry at production, distribution and retail levels. The responsibilities of the pharmaceutical industry in this area are outlined in the National Medicines Policy and the National Strategy for the Quality Use of Medicines. In addition to a range of areas of responsibility shared with other partners involved in the implementation of the National Strategy for the Quality Use of Medicines, that Strategy highlights the need for the pharmaceutical industry to be responsible for:

- continuing to develop safe and effective products to prevent, treat and cure illness or maintain health;
- marketing and promoting products in a way that facilitates quality of use;
- providing good quality, accurate, balanced information and education services that are conducive to the quality use of medicines; and
- discouraging information and education activities that are not conducive to the quality use of medicines.

Given that the pharmaceutical industry is an important stakeholder, it will be important to strengthen relationships with the industry in order to enhance Australia's capacity to reduce pharmaceutical drug misuse. Actively engaging with pharmaceutical industry representatives will also facilitate access to their extensive industry and product knowledge. This will ensure that all facets of the pharmaceutical industry including product development, production and sales activities are engaged in contributing to the objectives of this Framework. This will be particularly important when developing responses to the emerging threat of international Internet pharmacies. The media also has an important role to play in the realistic reporting of the benefits and harms that can arise from medication use.

Next steps

The Intergovernmental Committee on Drugs (IGCD) will be responsible for monitoring the implementation of the National Pharmaceutical Drug Misuse Framework for Action.

Given its holistic nature, the implementation of the Framework will involve the cooperation of a range of stakeholders. There are aspects of the Framework that are currently being implemented, others that can be implemented in the near future, while others are longer-term strategies.

The development of collaborative partnerships with other agencies and committees responsible for the oversight of some of the key priority areas and actions identified in the Framework will be crucial to its successful implementation and therefore to the reduction of pharmaceutical drug misuse and its associated harms.

There are a number of issues that are a high priority, but not all of these will be able to be implemented in the short term. The coordinated medication management system, for example, will be critically important to enhancing the quality use of medications such as opioids and benzodiazepines. Given the complexities involved, it will not be possible to fully implement this as a comprehensive system in the short term. Likewise, many of the structural issues contributing to pharmaceutical drug misuse, such as prescriber remuneration patterns and the level of access to non-pharmacological treatments will take longer to address.

There are, however a number of aspects of the Framework that can be implemented in the shorter term. The development and promotion of national guidelines for the treatment of pain,

mental health problems, sleep disorders and alcohol and other drug use problems, could begin in the shorter term. Likewise the development of protocols for pharmacists involved in the dispensing of opioids and benzodiazepines could commence soon, as could an examination of the extent to which different jurisdictional regulatory models impact on the misuse of these drugs.

It is important that the outcomes of the implementation of the Framework are evaluated. Correspondingly, the Framework contains a recommendation that an action research methodology be developed that assesses the intended and unintended outcomes of the Framework implementation.

Australia is well placed to intervene in the trajectory of pharmaceutical drug misuse problems before they reach the severity evident in other countries. This Framework will form the basis of this intervention.

PART TWO: THE FRAMEWORK

Goals

1. To reduce the misuse of pharmaceutical drugs and associated harms in Australia.
2. To enhance the quality use of pharmaceutical drugs without stigmatisation or limiting their accessibility for therapeutic use.

Focus

The Framework is underpinned by a focus on the quality use of prescription and non-prescription opioids and benzodiazepines. This includes the use of evidence-based non-pharmacological alternative therapies. The Framework seeks to minimise the intentional and unintentional misuse of these medicines and to develop approaches that could also be applied to other potentially problematic medicines.

Priority Areas

The Framework adopts a holistic approach to addressing these problems which is in keeping with the complex range of factors that contribute to pharmaceutical drug misuse. The Framework is consistent with Australia's National Strategy for the Quality Use of Medicines. Nine priority areas for action are identified. These were informed by an extensive consultation process involving written submissions, consultation workshops, a review of the literature, discussions with key experts and guidance from an Expert Reference Group and a Project Steering Committee.

Priority Areas

Actions

1 Coordinated medication management system

A coordinated medication management system is an on line, real time tool that provides information on patients' relevant medication usage for prescribers, pharmacists and regulators. It is important that such a system be linked to the regulatory and monitoring approaches outlined in

- 1.1 Progress implementation of the nationally-based and jurisdictionally consistent Electronic Recording and Reporting of Controlled Drugs (ERRCD) system which enables prescribers, dispensers and regulators to have real time online access to information concerning patients' access to prescription opioids and other Schedule 8 medicines.
- 1.2 Consider future enhancements to the ERRCD system to meet the characteristics of a comprehensive coordinated medication management system.

<p>Priority Area 4.</p>	<p>1.3 Where necessary, enhance the required regulatory infrastructure to respond to ERRCD system-generated data.</p> <p>1.4 Coordinate national education about the ERRCD system for health and welfare professionals and the broader community.</p>
<p>2 Supporting prescribers</p> <p>This area focuses on a range of strategies that enhance prescribing practice to minimise intentional and unintentional misuse. This includes the development of prescribing guidelines and workforce development measures.</p>	<p>2.1 Develop and/or promote national guidelines for the (non-pharmacological and pharmacological) treatment of conditions commonly implicated in the problematic use of these pharmaceuticals including:</p> <ul style="list-style-type: none"> a. Pain (acute, chronic non-malignant and cancer); b. Mental health problems (e.g. anxiety); c. Sleep disorders; and d. Alcohol and other drug use problems (including pharmacotherapy). <p>2.2 Explore options to enhance peer review mechanisms, practice enhancement approaches and disciplinary measures for prescribers who consistently and inappropriately prescribe outside the boundaries of the proposed guidelines.</p> <p>2.3 Enhance undergraduate, postgraduate and in-service education programs for the medical, health and human services workforces about the quality management of problems such as pain, mental health problems, sleep disorders and alcohol and other drug problems.</p> <p>2.4 Identify opportunities to better support prescribers who feel pressured by patients to provide medications inappropriately.</p>
<p>3 Supporting pharmacists and other health professionals</p> <p>This includes actions to enhance the role of pharmacists in medication management as well as a range of practice enhancement measures for this group. It also highlights the need for other health professionals to be more aware of and involved in the appropriate treatment options for conditions such as pain, anxiety and sleep disorders.</p>	<p>3.1 Explore opportunities to enhance the contribution that pharmacists can make to the care plans of patients.</p> <p>3.2 Review and, where necessary, enhance protocols for pharmacists concerning acceptable practice in the dispensing of these medications.</p> <p>3.3 Investigate options to improve access to undergraduate and in-service professional development programs for pharmacists to better utilise their professional abilities to enhance the quality use of these medications.</p> <p>3.4 Investigate options to establish or enhance peer review mechanisms and practice enhancement measures for pharmacists who dispense outside of protocol boundaries.</p> <p>3.5 Enhance the current pharmacy staged supply arrangements.</p> <p>3.6 Enhance the quality use of medicines in residential aged care facilities.</p> <p>3.7 Enhance the awareness of a range of health and welfare professionals regarding effective treatments for:</p> <ul style="list-style-type: none"> a. Pain (acute, chronic non-malignant and cancer); b. Mental health problems (e.g. anxiety);

	<ul style="list-style-type: none"> c. Sleep disorders; and d. Alcohol and other drug use problems (including pharmacotherapy).
<p>4 Regulation and monitoring</p> <p>This includes a range of enhancements to, and standardisation of, the ways medications are regulated and monitored and the ways in which data about pharmaceutical drugs are shared. The approaches outlined in this Priority Area should have close links to the coordinated medication management system (Priority Area 1).</p>	<ul style="list-style-type: none"> 4.1 Evaluate the extent to which different jurisdictional regulatory models impact on the misuse of these drugs and identify standardisation benchmarks for good practice. 4.2 Provide this Framework to the delegate of the Secretary of the Department of Health and Ageing for consideration in determining the need for a review of the scheduling of opioids and benzodiazepines. 4.3 Explore options to enhance the information sharing capacities of law enforcement and health agencies to reduce opportunities for theft, diversion, trafficking and fraud in pharmaceutical drugs. 4.4 Monitor and respond to emerging trends in local and international Internet pharmacies. 4.5 Consider the deliberations of the Working Group on the Promotion of Therapeutic Products regarding strengthening the self regulatory framework governing the relationship between health care professionals and therapeutic goods companies. 4.6 Assess the feasibility of removing opioid and benzodiazepine medications from advertising in pharmacy price lists. 4.7 Encourage the Pharmaceutical Benefits Advisory Committee and the Therapeutic Goods Administration to increase the emphasis placed on potential harms associated with pharmaceutical drug misuse in their decision making processes. 4.8 Explore opportunities to ensure that the enhanced monitoring and regulation of medications intended for human consumption does not enhance diversion from veterinary supplies.
<p>5 Structural factors</p> <p>This section addresses a range of issues related to access to services, medication management and prescriber remuneration which may contribute to pharmaceutical drug misuse.</p>	<ul style="list-style-type: none"> 5.1 Explore opportunities to improve access to treatments and services. <ul style="list-style-type: none"> 5.1.1 Explore options to improve access to multidisciplinary and non-pharmacological treatments for conditions such as chronic non-malignant pain, anxiety and insomnia. 5.1.2 Explore options to improve access to comprehensive, multidisciplinary, specialist pain facilities, particularly in the public sector. 5.1.3 Explore options to improve the access to comprehensive, multidisciplinary specialist sleep and mental health facilities, particularly in the public sector. 5.1.4 Explore options to improve the access that prescribers, pharmacists and patients have to

	<p>specialist alcohol and other drug treatment services and expertise.</p> <p>5.1.5 Explore opportunities to improve access to non-opioid adjuvant medications for pain conditions by encouraging sponsors to make submissions to the Pharmaceutical Benefits Advisory Committee for them to be listed on the Pharmaceutical Benefits Scheme.</p> <p>5.1.6 Explore opportunities to reduce current obstacles to opioid substitution therapy programs in Australia.</p> <p>5.2 Explore opportunities to enhance liaison in transitional medication management between hospitals and community settings.</p> <p>5.3 Where possible, enhance the range of medication pack sizes and/or dispensing options for Pharmaceutical Benefits Scheme medications.</p> <p>5.4 Promote utilisation by prescribers of Medicare Benefits Schedule items which remunerate and target medication review and/or non-pharmacological management of conditions such as pain and mental illness.</p>
<p>6 Health information and other consumer responses</p> <p>This section addresses a range of health literacy issues including problems related to the acceptability of non-pharmacological treatments, the accessibility of information, medication labelling and the protection of patients' rights.</p>	<p>6.1 Widen the acceptability of non-drug and non-opioid, non-benzodiazepine treatments for physical and psychological problems.</p> <p>6.2 Enhance the accessibility of information available to consumers regarding the potential harms associated with opioids and benzodiazepines.</p> <p>6.3 Further standardise the labeling of medicines in Australia.</p> <p>6.4 Promote the availability of review and appeal processes for patients and their prescribers who believe that access to target medications has been unfairly denied by enhanced monitoring and regulation.</p>
<p>7 Treatment and harm reduction</p> <p>This priority area focuses on the treatment needs of people with pharmaceutical drug misuse problems and the access that Australians have to the resources they need to reduce the harms associated with pharmaceutical drug misuse.</p>	<p>7.1 If necessary, re-orientate existing services or develop new programs to address the needs of the clients experiencing difficulties with problematic pharmaceutical use including both those who do, and those who do not, have a history of illicit drug use.</p> <p>7.2 Enhance the capacity of treatment services to meet the needs of ageing populations who have had longer-term exposure to pharmaceutical and non-pharmaceutical opioids.</p> <p>7.3 Enhance access to options available for police and courts to divert offenders involved in the problematic use of these medicines away from the criminal justice system.</p> <p>7.4 Ensure that Australia's needle and syringe programs have the ability to respond to the trend towards the misuse of pharmaceutical medications by injection.</p>

	<p>7.5 Better disseminate information concerning the potential harms and evidence-informed harm reduction measures to those involved, or potentially involved in the problematic use of these pharmaceuticals.</p> <p>7.6 Explore opportunities to expand needle and syringe programs into rural areas to a larger extent than is currently the case.</p>
<p>8 Technological responses</p> <p>This area seeks to implement measures such as tamper-resistant medications, pharmaceutical tracking measures and electronic prescribing to reduce pharmaceutical drug misuse.</p>	<p>8.1 Promote the use of tamper-resistant technologies for target medications.</p> <p>8.2 Consider the feasibility of implementing pharmaceutical pedigrees.⁴</p> <p>8.3 Enhance the use of electronic prescriptions to minimise the risk of dispensing errors and fraudulent alteration of prescriptions.</p>
<p>9 Data, research and evaluation</p> <p>This priority area contains strategies to enhance our understanding of the extent and nature of pharmaceutical drug misuse in Australia and appropriate responses.</p>	<p>9.1 Enhance and better co-ordinate pharmaceutical-related data collection and sharing processes to provide a more holistic picture of patterns of the prescription and utilisation as well as profiles and levels of harm.</p> <p>9.2 Conduct a range of specific research activities to focus on areas that could better inform public policy in this area.</p> <p>9.3 Develop an action research based methodology to assess the intended and unintended outcomes of the implementation of this Framework.</p>

⁴ A pharmaceutical pedigree is an audit trail that follows a drug from the time it is manufactured through the distribution system to a pharmacy.

Appendix 1 of the Framework describes in detail the rationale for the actions contained under the priority areas.

1. Coordinated medication management system

A system of coordinated medication management covering the prescribing and dispensing of relevant specified medications can be a powerful tool to enhance the quality use of medicines and enable prescribers and pharmacists (including those in hospitals) to make clinically appropriate decisions in relation to patient care.

These medicines are potentially dangerous and a coordinated medication management system would add to the current suite of tools established to reduce their misuse. It would act as a surveillance system that records the prescribing and dispensing details of specified medications for individual patients. Importantly, it would provide real time, on line data on prescribing, dispensing and supply to prescribers, dispensers and regulators as well as information on refusals to prescribe or dispense medications.

This has the potential to improve existing electronic clinical decision support systems by enabling real time identification of:

- irregularities in treatment, such as excessive prescription amounts and early repeat dispensing;
- drug-seeking by individuals attending multiple prescribers and pharmacies, hospitals, specialists and other settings;
- whether purportedly lost prescriptions have been filled; and
- patterns of dispensing which are suggestive of fraudulent activities undertaken to obtain medications (such as forgery and alteration of prescriptions) and flag problematic prescribing or dispensing patterns.

Where criminal activity is indicated, a coordinated medication management system could include provision for the sharing of this information with relevant agencies.

In developing a coordinated medication management system, a range of factors need to be taken into consideration including:

- having the potential to establish a national system which generates and provides access to information on the prescribing and dispensing of all relevant medications Australia-wide to prescribers and pharmacists involved in the care of individuals concerned, to regulators and to other agencies where indicated;

- developing the capacity to capture information on the prescribing of relevant Pharmaceutical Benefits Scheme, Repatriation Pharmaceutical Benefits Scheme and unsubsidised (including private) prescriptions;
- having the potential to have further capacity to capture data on a broad range of psychoactive medicines prone to misuse and have the capacity to adapt to emerging drugs of concern;
- ensuring that restrictions are not placed on those with a clinical need for the monitored medications;
- having appropriate protections for the privacy of patients through high levels of security, password-protection, anti-browsing software and an audit trail of all who access it;
- establishing expert and representative regulatory oversight and mechanisms for regular review;
- ensuring its use by prescribers and pharmacists is restricted only to informing treatment services for patients under their direct care and not for other purposes such as employment-related medical examinations, assessing insurance or compensation claims or compliance with bail or parole conditions;
- developing methods and criteria for detecting forged prescriptions, problematic prescribing and dispensing as well as drug seeking, and where criminal activity is indicated, providing for the sharing of this information with relevant agencies;
- applying limitations to automated warnings to prescribers and dispensers so as to limit warning fatigue;
- establishing links with advice and referral services for prescribers and patients;
- having the capacity to detect problematic prescribing within an individual medical practice (by different partners or locums);
- enabling a link with data concerning the provision of pharmacotherapy for drug dependence; and
- supporting its implementation with education programs for health practitioners and the broader community concerning its purpose in enhancing the quality use of medicines, so as not to stigmatise the use of monitored medications.

In implementing such a system, it will be important to ensure:

- that collaboration occurs between governments, consumers and professional groups to ensure an appropriate balance between protecting an individual's privacy, maximising patient safety and reducing the risk of medication misuse;
- that linkages are in place with the regulatory and monitoring approaches outlined in Priority Area 4; and
- account is taken of different legislation, local priorities and the resources of individual jurisdictions as well as the longer term potential for greater consistency across jurisdictions with regard to a legal and regulatory framework.

A coordinated medication management system would provide a prescriber with more timely and complete information with regards to a patient's recent medication history which would enhance their ability to make appropriate, safe and effective decisions in terms of prescribing additional medicines. As a result this has the potential to dramatically reduce 'prescription shopping' and, therefore, reduce the risk of inappropriate prescribing and dispensing and the incidence of drug misuse.

1.1 Progress implementation of the nationally-based and jurisdictionally consistent Electronic Recording and Reporting of Controlled Drugs (ERRCD) system which enables prescribers, dispensers and regulators to have real time online access to information concerning patients' access to prescription opioids and other Schedule 8 medicines

Under the Commonwealth Fifth Community Pharmacy Agreement, the Australian Government announced on 12 February 2012 the establishment of a new national real time, on line coordinated Schedule 8⁵ medication management system called the Electronic Recording and Reporting of Controlled Drugs (ERRCD) system.

The ERRCD system is based on the Drugs and Poisons Information System Online Remote Access (DORA) system implemented in Tasmania which has had a positive impact on prescribers and dispensers as a result of the improved information available to them to assist their decision-making.

The ERRCD system will provide real time information to prescribers and dispensers (as well as regulators) which can support their decision-making processes concerning the supply and dispensing of relevant Schedule 8 medicines. This includes supply of these substances in community settings, on discharge from hospitals and from hospital outpatient services. The system will also have capacity to detect forged prescriptions, problematic prescribing and dispensing as well as drug seeking.

If adopted by all jurisdictions, the new system would allow for managed access to information on the prescribing and dispensing of these medications Australia-wide.

A range of privacy safeguards will be in place including:

- access to the information collected through the system will be managed so that only those who require the information to dispense/prescribe or regulate will be able to view information relevant to their clinical practice;
- information will not be provided to third parties; and
- the system will have secure and encrypted information receipt and transmission processes, high levels of security, password-protection, anti-browsing software and an audit trail of all who access it.

⁵ Schedule 8 (S8) drugs and poisons, otherwise known as controlled drugs, are substances and preparations for therapeutic use which have high potential for misuse and dependence.

1.2 Consider future enhancements to the Electronic Recording and Reporting of Controlled Drugs (ERRCD) system to meet the characteristics of a comprehensive coordinated medication management system

The implementation of the ERRCD system should make a substantial contribution to the reduction of prescription opioid medicine misuse in Australia. Problems of pharmaceutical misuse are, however, not confined to the prescription opioids and other Schedule 8 drugs. Also important are psychoactive Schedule 4⁶ medicines drugs such as benzodiazepines, and some over the counter medicines (particularly those which contain codeine and others that have psychoactive effects).

It will be important for the ERRCD system to be reviewed and evaluated over time including to determine its capacity to incorporate information on these other medicines and fully function as a comprehensive coordinated medication management system.

1.3 Where necessary, enhance the required regulatory infrastructure to respond to ERRCD-generated data

The establishment of an ERRCD system will be a pivotal component in enhancing the quality use of prescription opioid medicines and other Schedule 8 drugs in Australia. The system will facilitate access to a large amount of data and it will be essential that the regulatory infrastructure is adequately resourced to effectively synthesise this data and respond to issues of concern at national and jurisdictional levels. The regulatory infrastructure will also need to be responsive to other data concerning diversion and misuse that ERRCD will capture in the future if it is expanded to include more medicines. In addition, the infrastructure should enable research to be undertaken to foster development of specific countermeasures to emerging problems as well as providing information support to prescribers and dispensers.

1.4 Coordinate national education about the ERRCD system for health and welfare professionals and the broader community

Australians will have a range of information needs about the ERRCD system. Key messages should include:

- details of the ways in which the initiative will enhance the quality use of these medicines;
- the role of the system in ensuring coordinated treatment and reducing harms associated with the poor quality use and misuse of these medicines;
- the ways in which the initiative may impact on obtaining these medications;
- the ways in which patients' privacy will be protected and the circumstances under which the information will be shared with other agencies (such as law enforcement); and

⁶ Schedule 4 medicines are medicines that require a prescription, but are not controlled drugs.

- information about the valuable role that these medications can play in the health and wellbeing of patients thereby countering the potential for any stigmatisation associated with their use.

2. Supporting prescribers

Enhancing the quality prescribing of medicines is central to this Framework and is consistent with the central objectives of Australia's National Medicines Policy. The National Strategy for the Quality Use of Medicines (2002) highlights that the quality use of medicines involves selecting management options wisely. It involves considering the place of medicines in treating illness and maintaining health and recognising that there may be more effective ways than using medicines to achieve these outcomes. Where a medicine is considered necessary it is important that the most appropriate medicine is selected by taking into account:

- the individual's characteristics;
- the clinical condition;
- risks and benefits;
- dosage and length of treatment;
- any co-existing conditions;
- other therapies;
- monitoring considerations; and
- costs for the individual, the community and the health system as a whole.

It is also necessary to monitor the outcomes of medications; minimise misuse, over-use and under-use; and improve health literacy in relation to the use of medications.

While the appropriate use of benzodiazepines and opioids can be very effective, it is widely acknowledged that there are indications of significant evidence-practice gaps in current prescribing practices in Australia. At times, these medications are prescribed inappropriately as first line treatments, for conditions for which they are not indicated or in a manner inconsistent with good practice. The reasons for this are complex and require multi-layered responses.

There is a need to enhance the standards of prescribing of these medications in order to improve the quality of their use. There is also a need to enhance patient outcomes by utilising evidence based, multi-disciplinary, non-pharmacological approaches to the treatment of a range of conditions.

2.1. Develop and /or promote national guidelines for the (non-pharmacological and pharmacological) treatment of conditions commonly implicated in the problematic use of these pharmaceuticals including:

- ***Pain (acute, chronic non-malignant and cancer);***
- ***Mental health problems (e.g. anxiety);***
- ***Sleep disorders; and***
- ***Alcohol and other drug use problems (including pharmacotherapy)***

These conditions can have a range of complex bio-psychosocial issues at their basis. Medications can be of benefit but they are not necessarily first line treatments and their use can lead to a reduction in the quality of outcomes for patients. Evidence-based treatment guidelines are necessary to more clearly define the circumstances under which various treatment options are most desirable. Such guidelines are important to support and guide clinical practice and to ensure that prescribers retain confidence in appropriately prescribing medications.

A range of clinical and procedural guidelines for the treatment of these conditions have been developed by a range of organisations over time. These existing guidelines vary in their currency, succinctness and accessibility, and there is some duplication and inconsistency between them. There is a need for promotion of relevant up-to-date existing guidelines and for the development of new consolidated guidelines where gaps exist.

A range of health professionals should be made aware of the guidelines. This is because a range of health professionals (apart from medical practitioners) now have the ability to prescribe relevant medications. In addition many different health professionals have a role in providing non-pharmacological treatments and it is therefore important that these treatments be evidence-based.

Guidelines should: accurately reflect the best available evidence and consensus of expert opinion; be succinct and consistent with the realities of busy clinical practice settings including those located in rural and remote areas; and be regularly updated. Guideline development should involve the use of internationally recognised methodologies such as those established by the Scottish Intercollegiate Guidelines Network (SIGN) or the Appraisal of Guidelines, Research and Evaluation (AGREE) Collaboration.

Guidelines should consider issues such as the importance of:

- comprehensive bio-psychosocial assessments prior to embarking on a course of treatment;
- informed patient consent and treatment agreements before trialling the use of opioids and benzodiazepines for the treatment of these conditions;
- appropriate early treatment of acute conditions to prevent progression to more chronic conditions;
- the differing roles of non-pharmacological and pharmacological treatments and their respective indications, strengths and limitations;
- adopting universal precautions⁷ in the prescribing of opioids and benzodiazepines

⁷The term 'universal precautions' was initially applied to infectious diseases because it is impossible for health care professionals to reliably assess risk of infectivity during an initial assessment of a patient. Thus precautions against infectious diseases need to be adopted for all patients. Likewise it is applied to the area of opioid prescribing (and potentially benzodiazepine prescribing) because without thorough assessment it is impossible to tell which patients may encounter difficulties with their use of these medicines. There are a number of facets of universal precautions which apply to opioid prescribing. These include: making an appropriate differential diagnosis and the identification and treatment of treatable conditions; psychological assessment including risk of addictive disorders; obtaining informed consent for treatment; the instigation of a treatment agreement; pre-post intervention assessment; a trial of medication; reassessment; regularly assessing the 'Four A s' of pain medicine (*analgesia, activity, adverse reactions,*

- potential patient referral pathways including their existence and nature and the indications for their use; and
- withdrawal regimes for benzodiazepines and opioids.

Guidelines should involve development of a hierarchy of care planning, monitoring and review processes that become increasingly stringent as prescribing practices become more risky and deviate from accepted clinical practice.

Increased risks could be associated with:

- use of medications for periods beyond that indicated in the guidelines;
- escalating doses or reaching identified critical dosages;
- the use of medications for conditions other than those consistent with recognised therapeutic guidelines;
- prescribing combinations of drugs known to be associated with high levels of harm (such as the concomitant prescription of benzodiazepines and opioids); or
- prescribing for patients assessed as being at risk of experiencing dose containment problems with these medications.

Guidelines should incorporate 'flags'  where increasingly high levels of prescribing risk require the prescriber to demonstrate comprehensive planning, peer review and/or consultation with regulatory authorities. All prescribers (including specialists) need to be involved in this hierarchy although specialists may have a higher threshold for 'flags'. The 'flags' could be linked to the electronic coordinated medication management system (see Section 1). Jurisdictional regulators could also use the guidelines as the basis for granting prescribing authorities and permits.

Guidelines should also focus on the potential for stigmatisation of patients who are appropriately using these medicines. This could be achieved by stressing the important role that the medicines can play in the treatment of many conditions.

In the context of pain management, it will be important that the evidence which informs the guidelines focuses not only on the alleviation of pain, but on the enhancement of functioning.

Existing and new guidelines will need to be widely publicised and their use encouraged in order to enhance the quality use of these medicines. This will involve identification and implementation of evidenced-based workforce development strategies to enhance clinical practice in this area. The National Prescribing Service and relevant medical colleges may be well placed to take lead roles in this regard.

While treatment guidelines are important, they are not, of themselves, likely to lead to major changes in clinical practice. They need to be supported by a range of workforce development measures, by providing prescribers with comprehensive information concerning their patient's

and aberrant behaviour); periodically reviewing pain and comorbidity diagnoses (including addictive disorders); and appropriate documentation (Gourley, Heit, & Almahrezi, 2005).

medication history (such as via a coordinated medication management system – see Section 1) and by addressing systemic issues that lead to sub-optimal patterns of prescribing (see Section 5).

2.2. Explore options to enhance peer review mechanisms, practice enhancement approaches and disciplinary measures for prescribers who consistently and inappropriately prescribe outside the boundaries of the proposed guidelines

Enhancing peer review mechanisms would require the support of the relevant Professional Registration Boards, colleges and jurisdictional regulators and would involve the implementation of targeted quality improvement measures as part of the professional development of identified clinicians. It will be essential to adequately resource professional organisations and training bodies to implement such practice enhancement measures.

2.3. Enhance undergraduate, postgraduate and in-service education programs for the medical, health and human services workforces about the quality management of problems such as pain, mental health problems, sleep disorders and alcohol and other drug problems

Enhancing education programs for quality prescribing for conditions such as pain is suggested at all levels from undergraduate through to post graduate and in-service. Human service providers encounter these conditions in clinical practice at a rate disproportionate to the extent to which they are included in practitioner education programs in either pre-service or post service environments. This may contribute to medications being used inappropriately in the first instance in preference to measures better supported by contemporary evidence. This has the potential to have adverse impacts on patients and can promote unhelpful coping responses.

These education programs should form part of broader workforce development activities. Workforce development activities are multi-faceted approaches which address the range of factors impacting on the ability of health professionals to function with maximum effectiveness. Workforce development activities should have a systems focus. Unlike traditional approaches, these are broad and comprehensive programs, targeting individual, organisational and structural factors. Effective workforce development goes beyond the provision of education and training to include issues such as recruitment and retention, workforce planning, professional and career development, and worker wellbeing. This broader approach to workforce development involves a wide range of individual, organisational, structural and systemic factors that can impact on the ability of the workforce to effectively and efficiently manage problems such as pain, mental health problems and sleep disorders and alcohol and other drug problems (Roche & Pidd, 2010).

2.4. Identify opportunities to better support prescribers who feel pressured by patients to provide medications inappropriately

Evidence exists about the profiles of practitioners who are most likely to be intimidated by patients (Magin, Adams, Sibbritt, Joy, & Ireland, 2005) such as those seeking inappropriate prescribing of medications. There is a need to proactively support these practitioners so that they are empowered to make appropriate prescribing decisions. This support could include better security, improved access to collegiate support and skill development in managing demands for medication.

3. Supporting pharmacists and other health professionals

Many health professionals are involved in the quality use of medicines. Foremost amongst these are pharmacists, as the central point of supply for prescription and many over the counter medications. Also important are the increasing number of non-medical prescribers. Pharmacists are in a unique position to enhance the quality use of these medications. They have an expert body of knowledge on medications, their quality use and potential dangers. Community pharmacists are important and accessible providers of primary health care services (including needle and syringe supply and opioid substitution therapy programs). Pharmacists are well placed to influence the ways in which patients use their medications and can relay concerns back to prescribers. However, greater support, training and appropriate reimbursement is required for these expanded roles of pharmacists. Specifically, greater support is required for pharmacists as they are provided with more information concerning the medication use histories of their patients and are therefore required to, at times, refuse patient requests for medications. It is also important that consumers become more aware of the roles and responsibilities of pharmacists in this area.

3.1. Explore opportunities to enhance the contribution that pharmacists can make to the care plans of patients

Pharmacists are an under-utilised resource in enhancing the quality use of medications. There is an opportunity for pharmacists to become more involved in multi-disciplinary case conferencing, medication reviews and engagement with prescribers with a view to enhancing the quality use of these medications.

3.2. Review and, where necessary, enhance protocols for pharmacists concerning acceptable practice in the dispensing of these medications

There is currently a lack of clear practice protocols for pharmacists to adopt in this area. These protocols should include:

- the nature and extent of counselling/advice to be provided to patients when dispensing these medications;
- warning signs exhibited by patients which may indicate poor quality medication use;
- procedures to be followed in the event that these warning signs are evident; and
- the correct procedures concerning the dispensing of repeat prescriptions at the same time as the original⁸.

⁸ Prescribers have the option of endorsing prescriptions under the National Health Regulation 24 (or for RPBS prescriptions endorse the prescription with 'hardship conditions apply') which permits dispensers to provide the repeat prescriptions at the same time as the original prescriptions. Unless very extenuating circumstances arise this should not occur without this endorsement on the prescription.

3.3. Investigate options to improve access to undergraduate and in-service professional development programs for pharmacists to better utilise their professional abilities to enhance the quality use of these medications

Given the pivotal role that pharmacists play in enhancing the quality use of all medications, they need an understanding of the protocols described above and contemporary perspectives concerning the roles and responsibilities of pharmacists when dispensing opioids and benzodiazepines.

3.4. Investigate options to establish or enhance peer review mechanisms and practice enhancement measures for pharmacists who dispense outside of protocol boundaries

The maintenance of high standards in dispensing is an important facet of this Framework. Peer review and practice enhancement measures play an important role. It may involve implementation of targeted quality improvement programs. Adequate resourcing would need to be made available to implement practice enhancement measures.

Such measures would also require the support of the Pharmacy Board of Australia, the Australian Health Practitioner Regulation Agency, the Pharmaceutical Society of Australia and pharmacy practice organisations.

3.5. Enhance the current pharmacy staged supply arrangements

Staged supply refers to arrangements whereby pharmacists (usually in response to a request from a prescriber) supply prescribed medicines to patients over a period of time in installments, rather than supplying the full quantity at the outset. Once dispensed, the medicine is held by the pharmacy and the instalments are provided to the patient according to an agreed regime. The consultations undertaken during the development of this Framework highlighted a growing demand for staged supply. In order to facilitate best practice, computerised pharmacy dispensing systems would need to be modified to accommodate the increased use of staged supply. These dispensing systems would also need to be supported by a coordinated medication management system (see Priority Area 1) to ensure that patients cannot attend multiple prescribers and dispensers. In addition, many pharmacies would need to have additional secure storage facilities to store patients' staged supply Schedule 8⁹ medications. There is also a need to have defined standards in place to ensure comprehensive communication between prescribers and pharmacists and to ensure best practice in dispensing and record keeping.

⁹ Schedule 8 (S8) drugs otherwise known as controlled drugs, are substances and preparations for therapeutic use which have high potential for misuse and addiction.

Although many of the medicines dispensed under staged supply arrangements are listed on the Pharmaceutical Benefits Scheme, this pharmacy service is not subsidised under the the Scheme. Consequently, the dispensing costs are either fully or partially met by the patient or absorbed by the pharmacy. Supporting patient groups with drug adherence difficulties by subsidising the cost of staged supply would have the potential to make a significant contribution to the quality use of medicines among these groups. This represents a key way to better utilise the existing infrastructure of community pharmacies.

3.6. Enhance the quality use of medicines in residential aged care facilities

Pharmacotherapy is a central component of medical care for older Australians. Approximately two-thirds of Australians over the age of 60 years regularly use four or more drugs (Elliot, 2006). The use of the benzodiazepines temazepam, oxazepam and nitrazepam peaks among Australians aged 90-94 on a defined daily dose per population per day basis (Hollingworth and Siskind, 2010).

Multiple medication use is particularly common among Australians living in residential aged care facilities, with each resident prescribed an average of almost seven drugs (Roberts et al. 1998).

There is a need to ensure that the standards of prescribing, dispensing and administering medications that occurs in these facilities contribute to the quality use of these medications. This is particularly important in light of the fact that those who administer medications to residents in aged care facilities may be less qualified compared with other health care settings.

3.7. Enhance the awareness of a range of health and welfare professionals regarding effective treatments for:

- ***Pain (acute, chronic non-malignant and cancer)***
- ***Mental health problems (e.g. anxiety)***
- ***Sleep disorders***
- ***Alcohol and other drug use problems (including pharmacotherapy)***

A range of health professionals including nurses, psychologists, physiotherapists and counsellors have a role in providing treatments for these problems and for educating consumers about available treatments. These health professionals need to be aware of the evidence base concerning the role of non-pharmacological and pharmacological treatment modalities for these conditions. This is in order that they can both enhance their role in the providing (particularly non-pharmacological) treatments for these conditions as well as enhance the health literacy of consumers concerning the strengths and limitations of differing approaches.

4. Regulation and monitoring

There is a range of limitations in the current regulations and coordination of information concerning the prescribing and dispensing of opioids and benzodiazepines and other drugs subject to diversion and misuse across jurisdictions. A significant issue for jurisdictions is the differing regulatory requirements and systems. In addition, the systems do not necessarily capture information on all relevant medicines. The monitoring of some benzodiazepines, for example, varies according to whether the Pharmaceutical Benefits Scheme makes a contribution to their cost. The sales of over the counter codeine-containing medications are not monitored at all.

A further difficulty experienced by the law enforcement sector is that existing pharmaceutical drug-related offences often vary between jurisdictions and attract lesser penalties than those that apply to illicit drug offences. This acts as an incentive for offenders to become involved in the illicit pharmaceutical trade. It can also be difficult for police to take action against individuals who claim that they have a legitimate reason to be in possession of medicines, when they are actually involved in trafficking. It will be important that law enforcement agencies are afforded a relevant level of access to information to enable them to respond, where appropriate, to any high level illicit pharmaceutical supply issues.

These problems also adversely impact on the quality use of medicines.

4.1. Evaluate the extent to which different jurisdictional regulatory models impact on the misuse of these drugs and identify standardisation benchmarks for good practice

There are currently significant differences between jurisdictions in the legislative and regulatory approaches in relation to Schedule 8 and Schedule 4 medications. Hence different authority, monitoring processes, dispensing quantities and penalties apply. This can not only complicate the prescription of these medicines but provides opportunities to exploit loopholes in the jurisdictional arrangements. It is important that the regulatory strategies be standardised across jurisdictional boundaries to enhance the quality use of these medicines and the exchange of essential information. It is also important that regulatory models support good practice as described in national clinical guidelines and link with the coordinated medication management system described in Priority Area 1.

4.2. Provide this Framework to the delegate of the Secretary of the Department of Health and Ageing for consideration in determining the need for a review of the scheduling of opioids and benzodiazepines

From time to time, problems arise with the misuse or poor quality use of specific medications. In the past in Australia for example, the oral capsule form of temazepam, was injected by some injecting drug users. This resulted in very severe health problems for many involved in this practice, including the requirement for amputations. No mechanism was in place to promptly respond to this problem. This meant that an extensive period of lobbying and other efforts were required which ultimately led to restrictions being placed on these capsules.

Similarly, problems are currently occurring with the benzodiazepine alprazolam, a potent short-acting benzodiazepine indicated primarily for moderate to severe anxiety disorders. This medication appears to be disproportionately associated with a range of problems such as seizures and rage responses, traffic accidents, crime-related harms and overdoses (DCPC, 2007 & Nielsen, et al. 2008)¹⁰.

The 2010 Medicines and Poisons Scheduling Reform made provisions for the delegate of the Secretary of the Department of Health and Ageing to consider matters of this nature on their own initiative or at the requests of the jurisdictions. The process also allows the delegate to make decisions regarding scheduling in a timely manner when there is a human health risk. An example of this occurred in the rescheduling of synthetic cannabinoids in early 2011. Further details of the scheduling process can be found at:

<http://www.tga.gov.au/industry/scheduling.htm>

This is the appropriate mechanism to review the current scheduling arrangements for these medicines.

4.3. Explore options to enhance the information sharing capacities of law enforcement and health agencies to reduce opportunities for theft, diversion, trafficking and fraud in pharmaceutical drugs

Currently the respective roles of the health and law enforcement sectors in responding to illicit supply and prescription shopping are not well defined. This may be due to the fact that large-scale trafficking in these substances is a relatively recent phenomenon. As a consequence, protocols enabling the sharing of information between police and health agencies are not well established. These information sharing problems arise on intra- and inter-jurisdictional levels. While it is anticipated that police would rarely have the need to access information on the pharmaceutical drug use of a consumer, where there are indications of high level supply offences, or an illicit trade in pharmaceuticals, this access would become important.

¹⁰ In addition during the consultation for the development of the NPDMFA, numerous stakeholders expressed a consistent level of concern about the current harmful patterns of alprazolam use in Australia.

The difficulties which police experience in accessing information currently held by the health sector and, at times, by different state/territory and national jurisdictions currently limit their ability to detect and prosecute a range of pharmaceutical drug-related offences. As a result, it is currently only possible for police to access relevant information when a problem with illicit supply has already caused significant levels of harm in the community. There are also few clearly established mechanisms through which the law enforcement sector can share information with health agencies about trafficking in, and poor quality use of, pharmaceuticals that come to its attention. These problems are major barriers to the investigation of these crimes, to measures to reduce prescription shopping and to the reduction of harm.

There is a range of privacy and legal issues which impact upon the ability to share information between health and law enforcement agencies. It is therefore important that legislation, protocols or memoranda of understanding be developed which facilitate the sharing of relevant information between health and law enforcement agencies. It may be useful to establish a sliding scale of seriousness of offences, or potential harm, to guide this sharing of information. In this way, evidence suggesting criminal activity would open the pathways to more comprehensive and detailed information sharing between these agencies. These approaches should be nationally consistent so that offenders cannot exploit differences between the levels of information sharing within and between jurisdictions. In developing a coordinated medication management system (see Section 1), it will be important that police have access to relevant information once specific requirements/criteria are met.

4.4. Monitor and respond to emerging trends in local and international Internet pharmacies

Internet pharmacies are a growing feature of the Australian and international pharmaceutical sales landscape. Instead of attending 'bricks and mortar' pharmacies, patients can order their prescription and non-prescription medications on line. These pharmacies can be of great assistance to those for whom accessing 'bricks and mortar' pharmacies is difficult. Internet pharmacies can be either located within Australia or internationally.

International Internet pharmacies are generally beyond the scope of Australian regulation because they are subject to the laws of the jurisdiction in which they are housed. This is a major concern in relation to the quality use of medicines because Australian regulators have little control over their activities. These pharmacies can, for example, dispense without a prescription medications which require a prescription in Australia and could therefore circumvent a range of measures implemented as part of this Framework. Many of these international Internet pharmacies bear no relation to traditional pharmacies and are, in reality, criminal enterprises with little interest in the safety of their patients.

Nevertheless, there are measures that could be implemented to limit their influence on the Australian pharmaceutical supply environment. This could include enhanced Customs and Border Protection Service detection activities at the international border. It could also include the provision of more comprehensive information for the public about the risks associated with the use of international Internet pharmacies. The risks include receiving counterfeit, substandard or

inappropriate medications and legal issues associated with attempting to import certain medications into Australia. The National Prescribing Service may be well placed to undertake this work.

The introduction of pharmaceutical pedigrees as discussed at 8.2 is also likely to aid in the identification of counterfeit medications and those imported from overseas. Also important is the need to ensure that the medications contained within Customs Regulations are aligned with other regulatory approaches, such as the scheduling of medicines. This is particularly important as far as Schedule 8 medicines are concerned.

It is anticipated that enhancing the regulation and monitoring of opioids and benzodiazepines in Australia could make international Internet pharmacies more attractive to some consumers. This will result in the need for greater vigilance concerning this issue.

It is essential to ensure that the same regulatory requirements that apply to 'bricks and mortar' pharmacies also apply to Australian-based Internet pharmacies. This includes requirements for patient assessment and counselling, the arrangements for the provision of repeat prescriptions and other measures intended to enhance the quality use of medications. These protocols could be developed by the relevant regulatory and professional groups.

4.5 Consider the deliberations of the Working Group on the Promotion of Therapeutic Products regarding strengthening the self regulatory framework governing the relationship between health care professionals and therapeutic goods companies

In 2010 a Working Group on the Promotion of Therapeutic Products was established to examine this issue. The ensuing Position Paper called on the therapeutic products industry to strengthen and standardise self-regulation through the use of codes of practice based on consistent industry-wide principles. The Position Paper indicated that strengthened self-regulation is the Government's preferred approach but foreshadowed that if appropriate arrangements are not developed, then further options to ensure consistent and appropriate industry practices will be pursued.

The results of the deliberations of the Working Group should form the basis of ongoing activities in this area.

4.6 Assess the feasibility of removing opioid and benzodiazepine medications from advertising in pharmacy price lists

The Therapeutic Goods Administration has developed the Price Information Code of Practice that describes the circumstances under which pharmacies can make medication price lists publicly available. There is a concern that advertising the price of opioid and benzodiazepine medications, even in price lists that comply with the code of practice, may promote their poor quality use. There are two aspects to this. The first is that the discount prices themselves may make the medications more attractive and act as an incentive for patients to seek them from

prescribers. The second is that larger pack sizes of the medications are often considerably cheaper on a per-dose basis than smaller packs. Consequently, patients may seek to influence prescribers to prescribe larger pack sizes than are therapeutically indicated, for the purpose of cost saving.

4.7 Encourage the Pharmaceutical Benefits Advisory Committee and the Therapeutic Goods Administration to increase the emphasis placed on potential harms associated with pharmaceutical drug misuse in their decision making processes.

Many of the pharmaceutical drugs subject to misuse can cause serious harms in non-patient populations and among patient populations using medications in an unintended manner. It is important that this is taken into consideration in the processes applied to approve the sale and Pharmaceutical Benefits Scheme-subsidisation of medicines in Australia. Where issues arise with pharmaceutical drugs, for example through diversion from licit to illicit use, problematic and non-medical use, expert Committees of the PBS (the Pharmaceutical Benefits Advisory Committee and the Therapeutic Goods Administration) should be encouraged to develop possible responses to the potential physical and criminal harms associated with this misuse.¹¹

4.8. Explore opportunities to ensure that the enhanced monitoring and regulation of medications intended for human consumption does not enhance diversion from veterinary supplies

Several of the opioid and benzodiazepine medications developed for human consumption are also used in veterinary practice. Alprazolam, for example, is used in veterinary practice to reduce anxiety symptoms in animals and as an adjunct to anaesthetics used in surgical and other painful procedures. It is important that the access that veterinarians have to this and other medications is not inadvertently reduced by the Framework.

¹¹ The primary objective of the PBS is to improve the health of Australians. The range of drugs and formulations available under the PBS provides a formulary of medicines to meet the health needs of the majority of the Australian community. The role of a drug product in meeting the health needs of the Australian community is therefore a primary consideration of the PBAC.

The primary role of the Pharmaceutical Benefits Advisory Committee (PBAC) is to recommend to the Minister for Health which drugs and medicinal preparations should be subsidised by the Australian Government under the Pharmaceutical Benefits Scheme (PBS). In doing this, PBAC is required by the National Health Act 1953 to consider both the effectiveness and cost of the proposed drugs and medicinal preparations. The PBAC considers submissions from industry sponsors of drug products, medical bodies, health professionals, private individuals and their representatives. For new products or new indications, however, it is normally the sponsor or manufacturer that holds the data required for such a submission.

The PBAC may also consider non-health outcomes, including aspects of the delivery of a health care intervention beyond the health gain obtained; for example, greater convenience or productivity gains to society. The valuation of non-health outcomes, however, is not straightforward and those outcomes might not be as influential in decision making as health outcomes.

The PBAC encourages the quality use of medicines (QUM) through the inclusion of cautions and notes in the PBS Schedule, the wording of PBS restrictions and the provision and publication of Australian drug utilisation data. It also supports educational activities promoting the appropriate utilisation of pharmaceuticals undertaken by the National Prescribing Service (NPS), particularly its Rational Assessment of Drugs and Research (RADAR) program.

Australian veterinarians have a long history of using measures to reduce the diversion of Schedule 4 and Schedule 8 medications. Nevertheless the implementation of this Framework may enhance the attractiveness of diverting these medications from veterinary sources. As a result it is important that the Australian Veterinary Association implements an education program to ensure that their members are aware of the potential for diversion of these medications for human use and to enhance their vigilance in this area. It will also be important to ensure that appropriate measures are in place to maintain the security of these medicines.

Should problems arise with misuse or multiple visits to various veterinary hospitals to obtain relevant medications, it would be possible to record the microchip registration numbers of animals receiving them along with client details and have these recorded in a central database. This would facilitate closer monitoring and regulation of this practice.

5. Structural factors

A range of factors can adversely impact on the ways in which medications are prescribed and used in Australia. These factors include barriers to accessing specialist assessment and treatment services, non-medication treatments and non-opioid treatment medications. There is also a range of structural factors which influence prescribing practices such as Pharmaceutical Benefits Scheme restrictions, prescriber remuneration patterns and care co-ordination issues.

5.1. Explore opportunities to improve access to treatments and services

5.1.1. Explore options to improve access to multidisciplinary¹² and non-pharmacological treatments for conditions such as chronic non-malignant pain, anxiety and insomnia

An imbalance exists between the strong evidence base supporting the use of non-pharmacological treatments (such as physiotherapy and cognitive behavioural therapy) for conditions such as chronic non-malignant pain, anxiety and insomnia; and their ready accessibility. The Pharmaceutical Benefits Scheme assures access to a wide variety of medications. The same level of accessibility is not, however, provided for many non-pharmacological treatments. It is therefore more likely that medications will be used in preference to non-pharmacological treatments even where a lower level of evidence exists for their efficacy as first line treatments.

A range of measures being implemented under Australia's National Health Reform program (Commonwealth of Australia, 2011) may address this anomaly. Medicare Locals, for example, aim to enhance patients' access to multidisciplinary care and promote broader access to services such as physiotherapy, psychology, practice nurses, nurse practitioners and clinical pharmacists.

While access to these treatments is currently problematic, it is important to increase the awareness of prescribers about the referral pathways that are available.

There is also a need to encourage multidisciplinary care of patients in other ways. This includes supporting case conferencing among health professions for patients with complex needs in relation to their use of these medications. Pharmacists have an important role to play in this regard.

¹² A multidisciplinary approach involves a variety of health and welfare professionals with varied but complementary skills that contribute to quality patient care.

5.1.2. Explore options to improve access to comprehensive, multidisciplinary, specialist pain facilities, particularly in the public sector

It is recognised that most pain patients will not need comprehensive, multidisciplinary, specialist pain treatment facilities. These services are only required for more complex cases. For this group, there is often a substantial waiting period to access the services needed and this can be particularly difficult for those living in rural and remote areas. This may result in patients not receiving a comprehensive multidisciplinary assessment in a timely manner and can result in poor quality medication utilisation. In addition, for a variety of reasons, patients are commonly prescribed opioids while awaiting access to pain clinics. This may further complicate their treatment when patients finally attend these facilities if they have become dependent on opioids.

As a result of difficulties in accessing pain clinics, patients whose needs would most appropriately be met by these clinics are, at times, being treated in opioid substitution therapy programs.

A further difficulty associated with pain clinics is that they may not have access to practitioners with expertise in treating alcohol and other drug problems. This makes it difficult for them to respond to patients who have complex needs in this area.

5.1.3. Explore options to improve access to comprehensive, multidisciplinary specialist sleep and mental health facilities, particularly in the public sector

Barriers to accessing specialist sleep and mental health facilities can result in patients not receiving comprehensive multidisciplinary assessments and can result in the preferential use of medication over more evidence-based treatments. These problems are particularly apparent in rural and remote areas.

5.1.4. Explore options to improve the access that prescribers, pharmacists and patients have to specialist alcohol and other drug treatment services and expertise

Those seeking treatment for pharmaceutical drug misuse problems can face a range of difficulties in accessing treatment. These can include difficulties in accessing services, problems with the extent to which services are oriented to meet the needs of those with pharmaceutical drug misuse problems, long waiting periods and treatment cost related issues, particularly for opioid substitution therapy.

Additionally, the mechanisms through which prescribers can obtain specialist alcohol and other drug treatment expertise are often not well known or developed. This means that prescribers can have difficulty gaining access to the expertise they need to assist with the management of patients with complex needs who, for example, may be escalating their medication usage. In particular there is a need to strengthen the hospital-based liaison and consultation

arrangements so that practitioners based in these settings can have access to the necessary expertise.

Australia also currently has a shortage of addiction medicine specialists. Greater emphasis should be placed on training more addiction medicine specialists using targeted funding for training positions. It will also be important to ensure that Medicare remuneration is appropriate to make the speciality a more attractive career path for young doctors. Targeted funding should also be made available for special skills training in addiction medicine for general practitioners to enhance the skills available as part of Medicare Locals.

5.1.5. Explore opportunities to improve access to non-opioid adjuvant medications¹³ for pain conditions by encouraging sponsors to make submissions to the Pharmaceutical Benefits Advisory Committee for them to be listed on the Pharmaceutical Benefits Scheme

Adjuvant medications can replace or reduce the requirement for opioid medications in the management of certain pain conditions. Currently several of the adjuvant medications which are both effective and have low side effect profiles are not subsidised on the PBS for this purpose. This means that patients are required to meet their full unsubsidised cost. By comparison, opioid medications are PBS-subsidised. This increases the likelihood that opioids will be prescribed, in preference to the adjuvant medications, particularly to financially disadvantaged patients.

These adjuvant medications are widely used in specialist pain clinics. Due to the fact that they are not available on the PBS to patients, these clinics often provide them to patients for free or at highly subsidised rates. As a result, pain clinics represent the only way that they can be afforded. Consequently, pain clinics tend to accumulate these patients, despite the fact that their care could generally be managed effectively by general practitioners. This, in turn, reduces the capacity of pain clinics to take on new patients.

The lack of access to suitable, PBS-funded, adjuvant medications is a major determinant of inappropriate opioid dose escalation (Submission to the National Pharmaceutical Drug Misuse Framework for Action).

5.1.6. Explore opportunities to reduce current obstacles to opioid substitution therapy (OST) programs in Australia

A range of obstacles currently exist in relation to OST program access including the ability to gain entry into programs, the lack of available OST prescribers, medication dispensing costs, having a limited range of OST options and difficulties in locating and travelling to prescribers and dispensers. When compared with the relative ease with which other pharmaceutical opioids

¹³ Adjuvant medications are used to assist in pain management, but their primary uses are for other disorders. These include conditions such as epilepsy and depression.

can be obtained from prescribers and dispensers, this can make OST programs comparatively less attractive. This is particularly problematic in rural and remote areas.

Australia may well see an increase in demand for OST in the future as a result of an influx of individuals seeking treatment for pharmaceutical drug misuse problems. It is therefore opportune to undertake a national review of OST provision to assess potential measures to respond to this problem. A range of issues should be included in a review of treatment capacity such as the range of OST options that are available (including an exploration of injectable OST) and an assessment of whether existing treatment services are appropriately oriented to meet the needs of individuals with pharmaceutical drug misuse problems and attract and retain them in treatment.

5.2. Explore opportunities to enhance liaison in transitional medication management between hospitals and community settings

A significant issue is that medications, particularly opioids and benzodiazepines, which are intended to be taken for a short period of time after discharge from hospital to aid recovery, are being taken for much longer periods. Hospital medication prescribing is increasingly being standardised, which can mean that discharge medications are prescribed when patients are admitted to hospital regardless of what their actual discharge medication requirements may be. Medications may also be provided on discharge in standardised pack sizes suitable for a prolonged period, when medication is only required for a few days. This is further compounded by the fact that patients now tend to be discharged earlier from hospital than was previously the case and therefore undertake a greater part of their recovery at home. General Practitioners can also find it difficult to stop medications prescribed in hospital because of patient expectations of on-going access to them. In addition, these practitioners may be unwilling to cease medications prescribed by treating doctors in hospitals. A further issue is that hospital discharge summaries may not reach general practitioners for some weeks after the patients have been discharged. This means that, in the interim, medications may be continued by general practitioners while awaiting this information.

Hospital pharmacists have a key role in ensuring that the amount of discharge medication is appropriate for the expected duration of pain. In addition, where patients have a regular community pharmacy, clear communication between the hospital, general practitioner and community pharmacy would also assist in the transition from hospital to community.

The current transition coordination problems can result in patients becoming dependent on these medications which increases the difficulties associated with ceasing them.

The Australian Pharmaceutical Advisory Council (APAC) developed Guiding Principles to Achieve Continuity in Medication Management (APAC, 2005). These Principles stress the need for:

- the provision of leadership by health care managers to ensure that systems are in place to enable continuity of medication management;

- health care professionals and managers to share responsibility with consumers and/or their carers for all aspects of medication management;
- joint and individual accountability among health care professionals and managers to implement activities that enhance continuity of medication management;
- an accurate and complete medication history to be obtained as early as possible in each episode of care;
- assessing current medication management;
- developing a medication action plan;
- the provision of medicines information to consumers;
- the provision of ongoing access to medications until the consumer's next episode of care;
- the provision of comprehensive and accurate information to the health care provider continuing the patient's care; and
- the evaluation of medication management.

These principles should also form the basis of addressing problems related to transitional medication management of opioids and benzodiazepines.

5.3. Where possible, enhance the range of medication pack sizes and/or dispensing options for Pharmaceutical Benefits Scheme medications

This Framework addresses medicines, particularly benzodiazepines, which should be reserved for short term use only and used as part of a broader treatment plan over 2-4 weeks. The large pack size of some medications available may not reflect their intended short-term use. This is a particular issue for some patients discharged from hospital on Pharmaceutical Benefits Scheme-subsidised medications. It is also an issue for patients presenting with conditions such as anxiety and insomnia who can receive quantities of benzodiazepines which last longer than the recommended period of usage. This can lead to the development of tolerance and dependence which may be difficult to reverse.

It may be preferable to have smaller 'starter-packs' of these medications available which are more aligned to the evidence concerning their period of utility. The use of these 'starter packs' would then require review by a prescriber within the period of time for which the evidence suggests the medications are of benefit. These 'starter packs' would also give prescribers a further option when presented with a patient who is unknown to them, who is requesting the medications which are the focus of this Framework.

In addition, pharmacists do have the capacity to break up packs of medication in response to requests from prescribers. While this may be problematic for some pharmacists, it is an option that may address some of the problems associated with the provision of pack sizes that are larger than clinically indicated. An educative process is required for prescribers and pharmacists to highlight this option. This process should highlight that prescribers have the option to prescribe less than the maximum quantities and repeats available on the PBS.

*In many instances the pack sizes of opioids available through the PBS do not reflect evidence based practice nor support appropriate use of these medicines. The rules governing the PBS do not always support the appropriate use of these medicines
(Submission to the National Pharmaceutical Drug Misuse Framework for Action).*

5.4. Promote utilisation by prescribers of Medicare Benefits Schedule items which remunerate and target medication review and/or non-pharmacological management of conditions such as pain and mental illness

Medicare Australia remuneration patterns can act as financial disincentives in the management of complex cases and can make it unviable for prescribers to allocate sufficient time to patients to conduct comprehensive bio-psycho-social assessments. Prescribers need to be appropriately remunerated for the care of patients requiring lengthy assessment for conditions such as chronic non-malignant pain.

Consequently, there is a need to monitor the Medicare Benefits Schedule to ensure that they accurately reflect the amount of time required to meet the needs of patients with complex conditions. There is also a need to ensure that prescribers are aware of and utilise the Medicare Benefits Schedule items that can remunerate them for the provision of these services.

Management of conditions such as anxiety, insomnia and chronic non malignant pain require considerable input of time and effort from GPs in the form of non-pharmacological methods such as cognitive behavioural therapies, ongoing counselling, and patient education. GPs often have limited time to spend on these therapies due to pressures of the number of patients they are required to see, and most feel pressured by patients to prescribe medication. Many GPs feel there is insufficient incentive and support to manage these conditions successful with some feeling inadequately prepared and of the opinion that subsidised training should be available.

(Submission to the National Pharmaceutical Drug Misuse Framework for Action)

6. Health information and other consumer 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 ensuring the quality use of medicines and the wisdom of their experience. Similarly, consumers are key partners in the National Pharmaceutical Drug Misuse Framework for Action. There are a number of aspects to this.

There is a need to address a range of health literacy needs¹⁴ including consumer expectations about medication being the first line treatment in a range of conditions. There is also a need to ensure that medication labelling is standardised and easy to read.

6.1. Widen the acceptability of non-drug and non-opioid, non-benzodiazepine treatments for physical and psychological problems

There is a need to have a range of measures which aim to enhance health literacy regarding the role of medications in health care in Australia. These measures should target:

- consumers;
- parents and primary caregivers who are instrumental in forming early attitudes and behaviours concerning the use of medications;
- family health and parenting professionals who inform, guide and educate parents and children on the responsible use of medications;
- school and community-based educators who deliver drug education and drug prevention programs and initiatives;
- community drug information providers, notably the government and non-government agencies which supply information resources and/or services; and
- providers of residential care facilities.

While medicines play an important role in the treatment of a range of conditions, there is also a need to fundamentally change the ways in which many Australians perceive the role of medications in responding to physical and psychological problems. The belief that 'there is a pill for all ills' can place pressure on prescribers to use pharmacological treatments in preference to potentially more effective measures. Likewise, it is important to ensure that consumers understand current best practice principles in the quality use of medicines and their rights and responsibilities in relation to this aspect of their health care.

There is also a need to change perceptions concerning the accessibility of Schedule 3¹⁵ medicines (pharmacist only medicines). While Schedule 3 medicines do not require a

¹⁴ 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. Low levels of health literacy can reduce the success of treatment and increase the risk of medical errors.

prescription, this does not imply that consumers have an automatic right of access to them. Pharmacists are legally required to confirm a therapeutic need for the supply of Schedule 3 medications and to ensure that the patient knows how to use them appropriately. Therefore, pharmacists play an important role in enhancing the quality use of these medications, which should not be undermined by consumer expectations of obtaining them.

The National Prescribing Service's Medicinewise program would form a solid foundation for the enhancement of many of these measures.

6.2. Enhance the accessibility of information available to consumers regarding the potential harms associated with opioids and benzodiazepines

Consumers can experience a range of harms associated with the use and misuse of these medications. Even when taken as prescribed they can lead to dependence and withdrawal symptoms on cessation. Other problems can arise when these prescription medications and over the counter codeine-containing medications are taken in ways other than as prescribed/recommended. Consumers need improved access to information on these harms in order to make informed decisions about their medication use and to fully participate in partnerships with health professionals. This is important to enhance the quality use of medicines and to optimise clinical outcomes. They also need readily understandable information on recognising dependence and addiction.

It is also important that consumers have access to easily understood information on the safe storage and disposal of these medicines including after the death of patients.

6.3. Further standardise the labelling of medicines in Australia

The quality use of medications could be enhanced by the standardisation of medication labels. The United States Pharmacopeia (2011) has established several recommendations for pharmaceutical labelling of prescriptions to improve the quality use of medicines by consumers, including:

- organising the prescription label in a patient-centred manner;
- simplifying the language;
- using explicit text to describe dosage/interval instructions;
- having the purpose for use on the label;
- improving the readability and format;
- providing labelling in patient's preferred language;

¹⁵ Schedule 3 (S3) medicines do not require a prescription and are only available for sale from pharmacies. They also require a pharmacist to provide advice and counselling on dispensing.

- including supplemental information; and
- standardising directions to patients.

The adoption of similar recommendations in the Australian context appear appropriate.

There are also problems associated with medications with the same active ingredients appearing with different labels (such as having the original branded name and the generic or pharmaceutical name). This can be confusing for patients, and in particular for the elderly and those for whom English is not their first language. Consequently there is a need to prominently display the generic name of medicines in specific branded drugs. Having the generic name in a larger, more prominent typeface on containers would enhance the recognition of the medicines they contain.

6.4. Promote the availability of review and appeal processes for patients and their prescribers who believe that access to target medications has been unfairly denied by enhanced monitoring and regulation

The key aim of this Framework is to enhance the quality use of these medications without reducing their appropriate accessibility or stigmatising that use. In doing so, it will be important that individuals are not adversely affected. Patient responses to treatment regimes can be highly variable. At times some patients respond well to treatment regimes that sit outside conventional practice.

As a result there is a need for patients to have access to a clearly defined appeal process involving suitably qualified individuals to ensure that their rights are protected.

7. Treatment and harm reduction

A range of health responses for people having difficulties with pharmaceutical drug misuse form an integral part of this Framework. Pharmaceutical drug misuse problems are complex and occur along a spectrum, ranging from unintentional through to intentional patterns of misuse. The problems include iatrogenic dependence stemming from the use of medications as prescribed, dose containment difficulties, harms associated with the paracetamol or ibuprofen contained in over the counter codeine-containing medications and problems associated with the injection of oral medications. The injection of pharmaceutical drugs also poses significant risks for the spread of blood borne diseases.

Health responses are required to respond to the wide variety of harms associated with pharmaceutical drug misuse. Many of these responses could be undertaken by general practitioners, while others, will require drug treatment facilities or other specialist services. The range of responses could include brief interventions, counselling and support programs and inpatient or outpatient withdrawal management services.

It is also important to have harm reduction programs in place for those who are currently using these medications in harmful ways (such as injecting oral medicines). This group requires access to information about the ways in which the harm related to injecting drugs in general and pharmaceutical drugs in particular can be reduced, access to injecting supplies that can make these patterns of use safer and referral options into primary health care and treatment facilities if required.

7.1. If necessary, re-orientate existing services or develop new programs to address the needs of the clients experiencing difficulties with problematic pharmaceutical use including both those who do, and those who do not, have a history of illicit drug use

The extent to which individuals without a history of illicit drug use, who are experiencing difficulties with their use of pharmaceutical drugs, would be attracted to current drug treatment services in Australia is unclear. In any event, it is most unlikely that the current treatment system has the capacity to cope with an influx of new clients seeking treatment for pharmaceutical drug-related problems. It is therefore opportune to undertake an examination of Australia's capacity to meet the treatment requirements of increased numbers of individuals experiencing difficulties with pharmaceutical drug use. This should include an examination of non-traditional and other treatment modalities.

While many patients are having their needs met by existing programs, it is also likely that new models of treatment delivery will be required for the spectrum of patients experiencing difficulties with pharmaceutical drug misuse. In doing so, it will be important to avoid the creation

of a two-tier treatment system; one tier for those without a history of illicit drug use and a second tier for those with a history of illicit drug use. This would only serve to further marginalise those with a history of illicit drug use.

7.2. Enhance the capacity of treatment services to meet the needs of ageing populations who have had longer-term exposure to pharmaceutical and non-pharmaceutical opioids

Evidence is emerging about the deleterious longer term impacts of exposure to opioids. These impacts include opioid-induced inhibition of the hypothalamic-pituitary function (leading to problems such as loss of bone density and sexual dysfunction), hyperalgesia and the requirement for more complex pain management interventions. These individuals have particular needs in the area of pain management and further research is required to better understand and respond to their health service needs.

7.3. Enhance access to options available for police and courts to divert offenders involved in the problematic use of these medicines away from the criminal justice system

The key interest of the law enforcement sector is in responding to offences such as the trafficking in, and theft of, pharmaceutical drugs. It also has a role in ensuring that those who are using these medications in problematic ways, but are not involved in major offences, have mechanisms through which they can be referred to appropriate intervention programs. It is therefore important that, where required, diversion programs are made available and more accessible to cater for those whose problematic use of pharmaceutical drugs has led to criminal justice system contact.

7.4. Ensure that Australia's needle and syringe programs have the ability to respond to the trend towards the misuse of pharmaceutical medications by injection

Needle and syringe programs (NSP) represent a critically important mechanism to reduce the harm associated with the injection of pharmaceutical drugs, particularly those which are intended to be taken orally. As with the injection of illicit drugs, the injection of pharmaceuticals poses risks such as vein damage and the spread of blood borne diseases. The National Needle and Syringe Strategic Framework 2010-2014 (Commonwealth of Australia, 2010) articulates a number of key priority directions which are also relevant to this facet of the National Pharmaceutical Drug Misuse Framework for Action. These include:

- The establishment of national standards across primary, secondary and community pharmacy NSPs;
- Increasing the availability of injecting equipment where the evidence suggests this could be of benefit (in the context of the National Pharmaceutical Drug Misuse Framework this

might include the free or highly subsidised syringe-driven filters¹⁶, winged infusions¹⁷, larger bore barrelled syringes¹⁸ and naloxone);

- Standardising the collection of data to provide greater insight into current injecting practices and risks, the scale of injection of pharmaceuticals and strategies to reduce the associated harms;
- Enhancing peer education programs in this area;
- The development of national core training areas for NSP workers;
- Enhancing the pathways available for NSP workers to refer clients to other services; and
- Improving and expanding the evidence base supporting the activities of NSPs.

7.5. Better disseminate information concerning the potential harms and evidence-informed harm reduction measures to those involved, or potentially involved in the problematic use of these pharmaceuticals

The problematic use of these pharmaceuticals brings with it a range of risks including overdose, the risk of blood borne diseases and problems associated with the injection of medications intended to be taken orally. There is a need to enhance the evidence base about effective harm reduction measures and to disseminate this information in a targeted manner. Needle and syringe programs would represent one logical mechanism through which to disseminate this information.

While needle and syringe programs are an important mechanism in this regard, it is important to note that many people who inject drugs obtain their injecting equipment from automatic dispensing machines and pharmacies and therefore do not access primary NSP services. Reaching these 'hidden populations' to provide adequate educational information will be a significant challenge.

7.6. Explore opportunities to expand needle and syringe programs into rural areas to a larger extent than is currently the case

The injection and problematic use of these pharmaceutical medications appears to be more frequent in rural, compared with urban settings (Day et al. 2005). It will therefore be important that appropriate harm reduction measures are focussed in both rural areas and urban settings, with an emphasis on redressing imbalances in service provision in rural areas.

¹⁶ Syringe-driven filters make it possible to filter material which is to be injected. A syringe is attached to the filter which is used to force the liquid drug through the filtering media. Large particles are retained in the filtering media.

¹⁷ Winged infusion sets (or butterfly needles) are used for intravenous injection. The needle that is inserted into the vein is stabilised by an attached piece of plastic shaped like butterfly wings. The needle is attached to a flexible tube into which the drug is injected.

¹⁸ Larger bore barrelled syringes are syringes with a larger diameter bore and are more commonly used to inject pharmaceutical drugs.

8. Technological responses

Technology can offer a range of ways in which the pharmaceutical drug misuse can be prevented. These include changes to the ways in which medicines are formulated, improving tracking systems for medications and making prescriptions more secure.

8.1. Promote the use of tamper-resistant technologies for target medications

Broadly there are three approaches to the use of tamper-resistant technologies, namely:

- 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.

The pharmaceutical industry has indicated its preparedness to consider tamper-resistant technology.

While the use of these measures should be promoted, it will be important that they do not inadvertently make the use of these substances more harmful.

8.2. Consider the feasibility of implementing pharmaceutical pedigrees

A pharmaceutical pedigree is an indelible marking on medicines that creates an audit trail that enables recording of a medication from the time it is manufactured through the distribution system to a pharmacy and even to the patient level. Bar coding and 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 was able to be traceable to the tablet or at least blister pack level. This would enable police to determine the identity of the last person with authority to be in possession of the medicines. This, in turn, would assist them to identify points of diversion. It would also help to identify counterfeit medicines or those that have been brought into Australia from sources such as international Internet pharmacies.

8.3 Enhance the use of electronic prescriptions to minimise the risk of dispensing errors and fraudulent alteration of prescriptions

Electronic prescribing reduces errors during the dispensing process by circumventing the need to transcribe the hard copy prescriptions into the dispensing program. In addition the electronic scanners recommended as best practice for dispensing in pharmacies further minimise the risk

of dispensing errors. Electronic prescribing involves the transcription of a prescription into an electronic format which is subsequently encrypted and sent to a secure gateway where it can be retrieved at the patient's pharmacy of choice. Importantly this also reduces opportunities for the illegal alteration of prescriptions. The Fifth Community Pharmacy Agreement contains an incentive for pharmacies to utilise electronic prescriptions.

As an interim measure, the use of distinctively coloured prescription stationary for Schedule 8 prescriptions could reduce the extent to which any prescription can be forged in order to obtain Schedule 8 medicines.

9. Data, research and evaluation

There is currently a range of gaps in our understanding of the extent and nature of pharmaceutical drug misuse problems in Australia. This stems from the fact that this is a relatively recent phenomenon and consequently the monitoring and other processes required to focus on this problem are not well developed. There are two aspects to this. The first is the need to enhance the collection of a range of data that provides a clearer picture of patterns of pharmaceutical utilisation and harm. The second is to undertake focussed research that could better inform policy in this area.

9.1. Enhance and better co-ordinate pharmaceutical-related data collection and sharing processes to provide a more holistic picture of patterns of the prescription and utilisation as well as profiles and levels of harm

There is a need to improve information collection and sharing to achieve a better understanding of patterns of medicines utilisation and problems from a public health perspective. There is also a need to collect national data on issues such as:

- mortality;
- pharmaceutical drug-related Emergency Department visits;
- ambulance call outs;
- overdoses;
- sobering up service admissions;
- harms related to the injection of pharmaceuticals intended to be taken orally;
- pharmaceutical-related road trauma; and
- poor parenting related to problematic pharmaceutical drug use.

Also required is the development of a nationally consistent data collection and categorisation system for law enforcement agencies for recording seizure and offence data related to pharmaceutical drugs.

9.2. Conduct a range of specific research activities to focus on areas that could better inform public policy in this area

Specific activities might include:

- the insertion of questions into the National Drug Strategy Household Survey to gain a clearer picture of patterns of pharmaceutical use and problems in Australia;
- research which examines the extent and nature of treatment needs of the group of patients experiencing difficulties with problematic pharmaceutical use who do not have a history of illicit drug use;

- research that examines the current nature and extent of treatment of pharmaceutical drug problems in primary care settings;
- research to determine the extent of treatment needs of, and service profiles required for, the group of patients experiencing difficulties with problematic pharmaceutical use who also have a longer-term history of (licit or illicit) pharmaceutical drug use;
- research to better understand the ways in which the poor quality use of these medications impacts upon disadvantaged members of the community such as Indigenous Australians, Australians from non-English speaking backgrounds, those living in rural and remote communities and refugees and how this could be addressed;
- research to determine the ways in which the harms associated with the poor quality use of these medications might best be minimised (such as minimising the harms associated with injecting oral medications);
- research which focuses on the mechanisms involved in the diversion of pharmaceuticals onto the illicit drug market including the extent of theft and other loss from the supply chain;
- research into the extent of organised criminality associated with the illicit sale of pharmaceutical drugs;
- research into the extent and nature of other pharmaceutical drug-related harms including driving while affected by pharmaceuticals, the impact of problematic pharmaceutical misuse on parenting and patterns of family violence; and
- research into pain and dependence treatment needs and the efficacy of different treatment modalities.

9.3. Develop an action research based methodology to assess the intended and unintended outcomes of the implementation of this Framework

The implementation of this Framework represents an important step towards enhancing the quality use of these medications. In the implementation of any such measure there will be intended and unintended outcomes. It will be important to be able to detect, report on and respond to these outcomes in a timely manner. It is for this reason that participatory evaluation methodologies need to be developed that provide timely information to allow regulators, prescribers and pharmacists to respond to issues as they arise. The development of measures described in priority area 9.1 will be very important in this regard.



APPENDIX I: THE NEED FOR A FRAMEWORK

Australia is experiencing an increase in the prescription of opioids and significant levels of harms associated with the patterns of use of opioids and benzodiazepines.

Prescription and non-prescription opioids

Over the past two decades Australia has seen an increase in the prescribing of certain opioid medications. Of particular importance is the increase in the prescribing of slow release formulations of these medications.

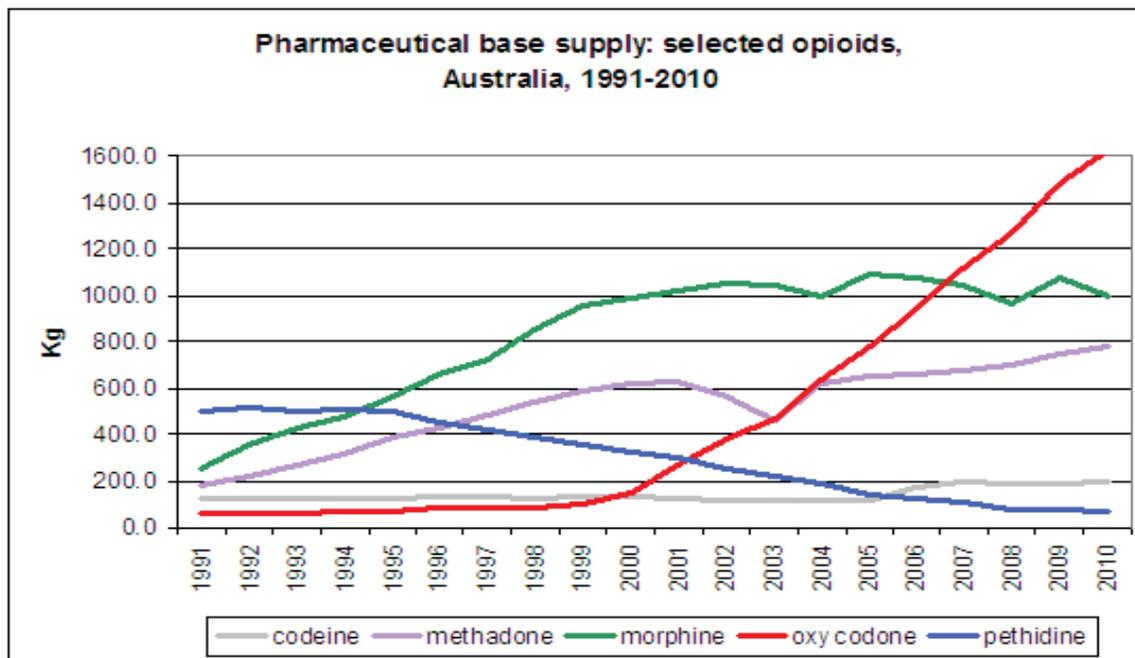


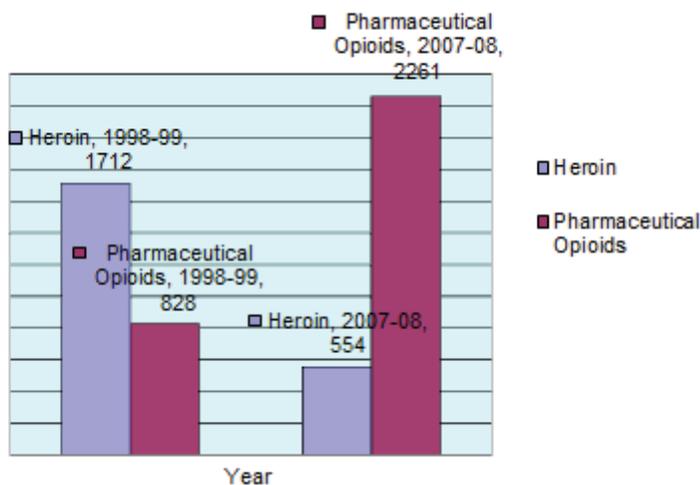
Figure 1. Pharmaceutical Base Supply: Selected Opioids Australia 1991-2010 (Dobbin, 2011)

Figure 1. shows an increase in the supply of methadone, morphine, codeine and in particular oxycodone between 1991 and 2010, while the supply of pethidine has declined. Between 31 December 1991 and 31 December 2010 the Australian population increased by 29% [Australian Bureau of Statistics, (1992) & Australian Bureau of Statistics (2011)]. During this time there was an increase of 228% by weight in the pharmaceutical opioid base supply to Australia (data provided by Dobbin, 2011).

The increase in supply of most of these medications is not necessarily problematic of itself. If this increase represented a quality use of these medications, then the Australian community would be deriving a concomitant level of benefits (such as those noted in this Framework). Unfortunately, as is discussed below, the increase in supply has been accompanied by an increase in harms. The increase in harms is following trends seen in other developed countries

such as the United States (Centers for Disease Control and Prevention, 2010) and Canada (Dhalla, et al. 2009). A timely response to pharmaceutical drug misuse problems will enable Australia to intervene in these problems before they reach the extent of harms experienced in other countries.

Experience from the US shows the risks of doing nothing in terms of real time monitoring; the dangers of uncontrolled doctor shopping and illicit diversion...
 (Submission to the National Pharmaceutical Drug Misuse Framework for Action).



Hospitalisations for heroin/other opioid poisoning Australia (AIHW, 2009)

Figure 2 Hospitalisations for heroin/other opioid poisoning Australia 1998-99 – 2007-08
 (Australian Institute of Health and Welfare, n.d.).

In 1998-99 pharmaceutical opioids accounted for 33% of opioid poisonings, but by 2007-08, this had grown to 80% (see Figure 2.). While it is clear that the cause of poisoning has shifted from heroin to pharmaceutical opioids, it is not clear whether those individuals who are currently experiencing poisonings have the same profile as those formerly being poisoned by heroin.

PBS Oxycodone supply and National Coroner's Information System Oxycodone-detected deaths Victoria 2000-09

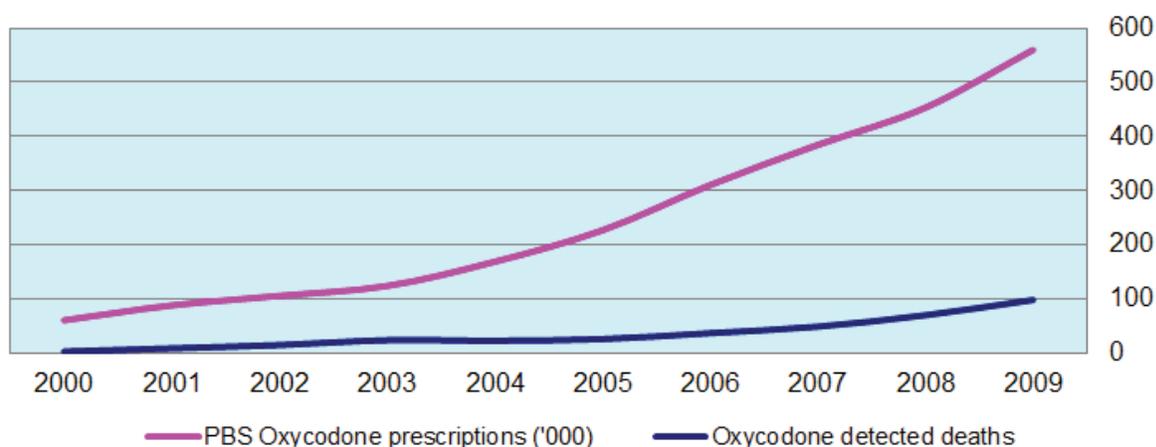


Figure 3 Pharmaceutical Benefits Scheme Oxycodone supply and National Coroner's Information System Oxycodone-detected deaths Victoria 2000-09 (Rintoul, Dobbin, Drummer & Ozanne-Smith, 2010).

Figure 3 shows that the increase in the PBS supply of Oxycodone in Victoria has occurred concurrently with an increase in the number of deaths in which this medication was detected. Rintoul et al. (2010) suggested that the increase in deaths was strongly and significantly associated with the increase in supply. They also reported that, because of methodological issues, their study was likely to have underestimated the number of Victorian drug-related deaths involving oxycodone. They also found that oxycodone-related deaths were over-represented in rural areas and in areas with high levels of social disadvantage. Data are not available to determine whether the relationship between oxycodone supply levels and deaths in which oxycodone is detected is evident in other jurisdictions.

Case Study 1

Colin, a tradesman, was involved in a major car crash when he was 18. He sustained life-threatening and painful injuries which required extensive surgery over a long period of time. Over time his use of prescription and non-prescription opioid analgesics and benzodiazepines increased and became a serious problem. He continued to be prescribed large quantities of these medications and attempted to detoxify from them on several occasions. Colin's very supportive parents tried their best to assist him. However their efforts were thwarted by inappropriate prescribing and dispensing practices which continued for much of the next 16 years. Also problematic was a lack of real time information available to his doctors and pharmacists about the extent to which he was prescription shopping. Colin died at age 34 of an overdose after apparently obtaining large amounts of benzodiazepines and oxycodone from his doctor.

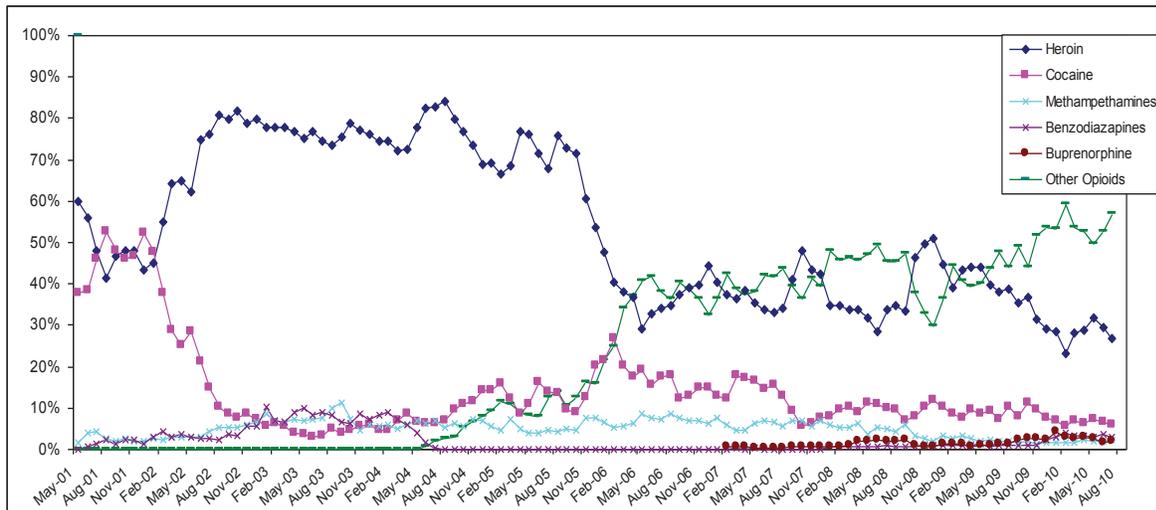


Figure 4 The proportion of users of the Sydney Medically Supervised Injection Centre (MSIC) who injected different substances May 2001-August 2010 (MSIC, 2010).

A further harm associated with the misuse of pharmaceuticals, particularly opioids, is the injection of oral medications. Up until May 2006, heroin was the substance most frequently injected at the Sydney Medically Supervised Injection Centre (see Figure 4). Since then pharmaceutical opioids have predominated. While this represents a significant shift, caution should be used in generalising this data to the Australian population as a whole.

Similarly, 43% of respondents to a national survey of illicit drug users reported injecting morphine in the past six months and 28% reported injecting oxycodone (Stafford & Burns, 2011). The injection of oral medications is associated with infections, the deposition of pharmaceutical materials in blood vessels or organs, or the occlusion of blood vessels or organs (Drugs and Crime Prevention Committee, of the Parliament of Victoria, [DCPC], 2007).

The harms associated with pharmaceutical opioids are not confined to prescription only medications. Over the counter or non-prescription drugs are also an emerging problem. Foremost among these are codeine-containing analgesics especially those containing paracetamol or ibuprofen. Complications associated with the misuse of these drugs include liver damage, gastro-intestinal bleeding and/or perforation, renal failure, low potassium levels, anaemia, opioid dependence and death (Dobbin, 2008).

Case Study 2

A young woman in her early 20s had a past history of treatment with pharmacotherapy for heroin dependence several years previously. She had been taking 96 Nurofen Plus® a day for 4 ½ years, initially for pain. Without any warning symptoms she suddenly perforated a gastric ulcer that penetrated into her pancreas causing pancreatitis. She developed shock, was critically ill and extremely toxic. She required admission to the intensive care unit, intubation and life support. She spent many weeks recovering in hospital and was subsequently commenced on methadone to treat her opioid dependence.

Benzodiazepines

While the use of benzodiazepine medications can bring benefit to patients, there is also a range of problems that can stem from their use, particularly when they are not used in accordance with evidence regarding their efficacy. These problems include sedation, concentration and memory problems and chaotic behaviour and disorganisation. Dependence on these medications can result in withdrawal symptoms if dosages are rapidly reduced or ceased. That can be very difficult to treat. The medications can also lead to paradoxical aggression or the so called 'Rambo effect', which manifests as talkativeness, mania, anxiety and restlessness which, along with adverse impacts on driving while affected by these drugs can be of concern to police (DCPC, 2007). A further significant problem associated with benzodiazepines, particularly in the elderly, is falls and other injuries (Bartlett et al., 2009).

There is also emerging evidence linking the problematic use of the benzodiazepine alprazolam with a disproportionately large range of harms. These include overdose deaths, seizures and rage responses among users, as well as traffic accidents and crime-related harms (DCPS, 2007 & Nielsen, et al. 2008).

The problematic misuse of benzodiazepines by clients receiving opioid substitution therapy (OST) is common and places them at greater risk of overdose (Nielsen, Lee, Dietz, Dunlop & Taylor, 2007). The combined use of benzodiazepines and illicit drugs can also have adverse outcomes. Fifty five percent of heroin-related deaths that occurred in Victoria between 2004 and 2008, for example, involved benzodiazepines (Woods, Gerostamoulos & Drummer 2009).

Over the past decade the overall level of benzodiazepine prescription in Australia has increased somewhat but a significant change has occurred in the profile of benzodiazepines and z-drugs¹⁹ being prescribed. Between the years 2002-2007 the prescribing of the benzodiazepine alprazolam increased by one third, particularly on private (non-Pharmaceutical Benefits Scheme) prescriptions (Hollingworth & Siskind, 2010) (see Figure 5.). Data on the trends since then are not available.

¹⁹ Z-drugs are a group of non-benzodiazepine drugs with effects similar to benzodiazepines which are used in the treatment of insomnia. They are called Z-drugs because most have names starting with the letter 'Z'.

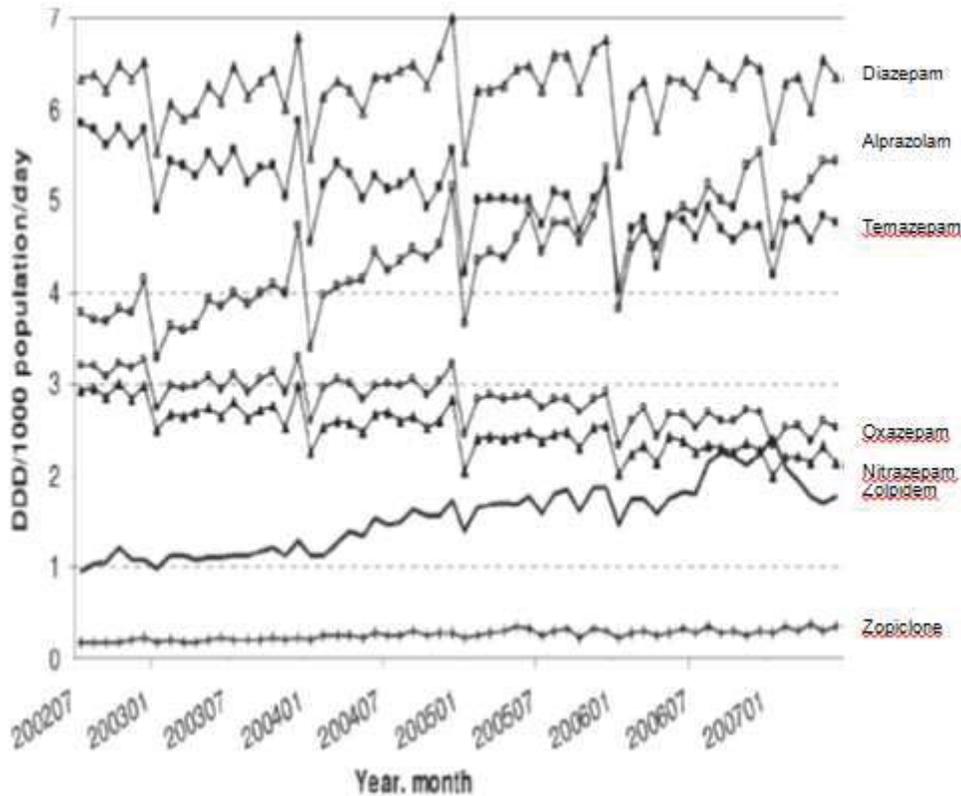


Figure 5 Total benzodiazepine and 'z drug' utilisation defined daily dose per thousand of Australian population per day July 2002 to January 2007 (Hollingworth & Siskind, 2010, p.284)

Are medications the best options?

At a broad level, a question arises regarding whether the status quo represents a quality use of these medications. Prescription opioids, for example, play an important role in the treatment of pain associated with serious injury, during recovery from major surgery, or for palliative care. The consultations undertaken in the development of this Framework revealed an apparent increase in the trend to use these medications to treat pain associated with relatively minor complaints, for which other approaches would be better suited.

Similarly, the appropriate role for prescription opioids in the longer term treatment of chronic non-malignant pain is uncertain. The available evidence suggests that non-pharmacological or non-opioid options may be preferable and lead to more sustained outcomes, particularly in relation to levels of patient functioning. The extent to which opioids are prescribed for this purpose in Australia is unclear but in America 95% of these drugs are prescribed for chronic non-malignant pain (RACP, 2009).

Despite the increase in the prescription of these medications in recent years, Australia's National Pain Strategy highlights major problems with the under-treatment of pain (ANZCA,

2010). This underscores the need for more effective approaches to pain treatment, especially those which do not rely on opioid medications.

Likewise, benzodiazepine medications are no longer the recommended first line treatment for problems such as anxiety and insomnia. Cognitive behavioural therapy (CBT) techniques are the preferred treatments for these conditions and lead to more sustained positive outcomes. If pharmacological treatments are required, the use of medications other than benzodiazepines (such as selective serotonin reuptake inhibitor antidepressants) is preferable. Where benzodiazepines are used to treat severe anxiety, the maximum recommended period of time for this treatment is 4 weeks (Department of Health [England] and the Devolved Administrations, DOHDA, 2007).

In treating insomnia, benzodiazepines should only be used for less than two weeks and ideally intermittently (e.g. 2-5 nights per week) (National Prescribing Service, NPS, 2010). The frequency with which benzodiazepines are prescribed in Australia and the periods for which they are prescribed, suggest prescribing practices are commonplace that are inconsistent with the available evidence concerning effectiveness.

There is mounting evidence that at least a proportion of benzodiazepine and opioid prescribing in Australia is unsupported by evidence of efficacy. This evidence-practice gap may be a cause of significant harm even where the drugs are taken as prescribed. The use of these medications when other approaches would be preferable, or for periods of time unsupported by evidence, means that other, potentially more effective approaches are not used.

Case Study 3

Ms J presented to a pain clinic at 4pm on a Thursday afternoon as she had run out of pain medications. She had moved from interstate for social reasons and requested the pain clinic continue her usual doses of prescription medications. Her usual medications were: morphine injections 30mg (six per day), gabapentin 300mg (three times a day), mirtazepine 30mg (at night), diazepam 25mg (three times a day) and temazepam 20mg (at night). The clinic she consulted was unwilling to prescribe the medications. After confirming the medication regime with her usual prescriber the pain clinic decided to wean her off the medications slowly. This was because of the risk of severe withdrawal reactions. One month later her doses were reduced to: Kapanol 50mg daily and diazepam 5mg twice a day. The patient was very grateful, her pain was better controlled and she was much more alert and enjoying life. She expressed concerns that the doctors had allowed her to have “been asleep for 15 years”.

Case Study 4

Barb is a 52 year old woman who had been using increasing doses of temazepam for several years. She was referred to the psychiatric unit for inpatient transfer to longer-acting diazepam with a view to long term withdrawal in an outpatient setting. She had a severe generalised anxiety disorder with mild agoraphobia and panic attacks and was also prescribed a number of other anxiolytic²⁰ medications. She was extremely anxious about reducing her benzodiazepines and the inpatient transfer was long and complicated but successful. During the planned protracted outpatient withdrawal of close to 6 months, she was referred for weekly cognitive behaviour therapy (CBT) to both support the withdrawal process and address long standing anxiety issues. Several weeks were spent focusing on increasing motivation, with the treating psychiatrist agreeing to maintain the initial dose until Barb was ready to start reducing. CBT focused initially on understanding and managing withdrawal symptoms and then later on addressing anxiety as she began to feel more comfortable with the idea of withdrawal. Strategies included managing anxiety related thoughts, exposure therapy for agoraphobia and cognitive and behavioural management of panic attacks. Psychological and medical management was closely tied and the treating team met at least monthly to ensure that the medication reduction was at a pace that Barb was able to psychologically manage. After 6 months her benzodiazepine use was at sub-therapeutic levels and was withdrawn completely by 8 months. She continued with monthly CBT for another year after that.

Law enforcement-related harms

Law enforcement-related harms associated with pharmaceutical misuse also appear to be increasing. Consultations held with law enforcement agencies in the preparation of this Framework indicated that a substantial market, in which illicit pharmaceutical drugs are being sold for profit, has emerged in Australia. This is not only a potentially very lucrative enterprise but it also undermines the regulatory systems in place that control the supply of certain medicines.

Police agency data indicate an increase in the number of police detections and seizures of pharmaceutical drugs over the past decade. Specifically, available jurisdictional data indicate an increase in the detection of pharmaceutical opioids by police. These medicines are now the

²⁰ Anxiolytic medications are used for the treatment of anxiety.

most commonly seized/detected pharmaceutical drugs in most jurisdictions where data is available. In contrast the number of seizures of benzodiazepines has been stable or declined.

Police are also experiencing an increase in harms related to intoxication with pharmaceutical drugs, including behavioural offences, driving while intoxicated and family violence issues. Crimes committed to obtain pharmaceutical drugs including theft, robbery, extortion and prescription forgery are also of concern.

The reduction in heroin-related health harms over the past decade and the corresponding increase in harms associated with pharmaceutical opioids has a corollary in the law enforcement sector. In 1998-99 there were 9,037 seizures of a total of 722.4kg of heroin in Australia (Australian Bureau of Criminal Intelligence, 2000). By 2009-10 this had fallen to 1,582 seizures of totalling 74.75kg (Australian Crime Commission, 2011). By contrast data provided by several law enforcement agencies for the preparation of this Framework highlights that law enforcement harms associated with pharmaceutical drugs, in particular opioids, have increased over the past decade. The NSW Police Force, for example, indicated that its officers were almost twice as likely to encounter pharmaceutical drugs in 2009 compared with 2001. The estimated number of NSW Police detections of opioid analgesics (other than those utilised for opioid substitution therapy) increased by 348% between 2001 and 2009. While this trend was not evident in all jurisdictions some jurisdictions recorded increases in detections.

This highlights the need for workforce development activities focussed on law enforcement agencies to assist them to respond to this problem.

Case Study 5

A 45 year old woman, who had no criminal history or prior involvement in the illicit drug market, came under financial strain due to a gambling problem. She became involved in selling oxycodone to pay off debtors. She obtained oxycodone from multiple doctors through the PBS and came to the attention of police when she presented a number of stolen and forged prescriptions. Police found that over a three month period alone, she had seen more than 44 different prescribers, had 56 medical consultations and received over 70 prescriptions. Over six months she obtained 1700 tablets of oxycodone which she was selling for approximately \$80 each. As a result of the police investigation, the woman was convicted for on-going supply of a prohibited drug and received a 3 year custodial sentence.

Economic harms

The economic harms associated with inadvertent or deliberate misuse of pharmaceutical drugs in Australia are difficult to quantify because they manifest in a range of ways. These include health care costs,²¹ deaths [Darke, Duflou, & Torok, (2011); Rintoul, Dobbin, Drummer, & Ozanne-Smith (2010) and Roxburgh, Bruno, Larance & Burns, (2011)] criminal justice costs and lost workplace productivity. In their analysis of the costs of alcohol and other drug abuse in Australia, Collins and Lapsley (2008) recognised that pharmaceutical misuse does have a significant economic impact, but it was not possible to quantify those costs.

²¹ This includes ambulance, emergency department and drug treatment costs, the costs associated with medical consultations used for drug seeking and the costs of the medicines which are the subject of misuse.

This issue has been studied in the US, however. In 2006, the estimated total cost of the non-medical use of prescription opioids was \$53.4 billion. Of this \$42 billion (79%) was attributable to lost productivity, \$8.2 billion (15%) was attributable to criminal justice costs, \$2.2 billion (4.4%) was attributable to drug abuse treatment and \$944 million to medical complications (2%). Five medicines, namely OxyContin®, oxycodone, hydrocodone, propoxyphene and methadone, accounted for two-thirds of the total economic costs (Hansen et al. 2011). Likewise Birnbaum et al. (2011) estimated this cost at \$55.7 billion in 2007 with work place costs (such as lost earnings from premature death and reduced earnings) representing 46% of the total.

Similar modeling has not been undertaken in Australia, but it is possible to quantify the Pharmaceutical Benefits Scheme (PBS) costs associated with increased utilisation of some medicines which are the focus of this Framework²². In the year ending June 2010, for example:

- there was a 27% increase in PBS-subsidised prescriptions²³ of fentanyl (an extra 93,650) at an additional government cost of \$9,616,000²⁴
- there was an 11.85% increase in PBS-subsidised prescriptions of oxycodone (an extra 212,385) at an additional government cost of \$8,345,500
- a total of \$1,261,671,000 was spent on 36,218,400 prescriptions for medicines related to the nervous system (PBS, n.d.).

In 2005 it was identified that the following number of prescriptions were provided to individuals identified as prescription shoppers under the Medicare Australia Prescription Shopping Program.

- Diazepam 5 mg: 227,203 supplies
- Codeine phosphate 30mg + 500mg paracetamol: 224,070 supplies
- Temazepam 10mg: 135,176 supplies
- Oxazepam 30mg: 120,733 supplies and
- Nitrazepam 5mg: 79,134 supplies (Wares, 2007).

If only a small proportion of the costs of these PBS-subsidised medicines are as a result of inadvertent or deliberate misuse, then the potential savings to the PBS that would be associated with enhancing the quality use of these medicines could be considerable.

Systemic factors impacting on the quality use of medications and opportunities for misuse

There is a range of systemic factors which influence prescribing practices and the quality use of these medications. The lack of real-time information available to prescribers and pharmacists concerning the medication histories of their patients can make it difficult for health professionals

²² Note that this does not in any way imply that this increase in use is as a result of misuse.

²³ Under Section 85 of the National Health Act 1953.

²⁴ In considering the cost changes it is important to note that this includes increases in the cost of the drug as well as increased utilization. The cost of fentanyl, for example, increased from \$103.64 to \$105.03 over this period.

to make informed decisions regarding patient medications, particularly as patients can attend as many different prescribers and dispensers as they wish.

Differences in legislation and regulatory approaches between jurisdictions mean that patients can move between jurisdictions in order to obtain medications. This complicates the detection and prosecution of offences such as prescription drug trafficking. This is further complicated by the national registration of health practitioners which means that, in some cases, a prescription written in one jurisdiction can be filled in another.

Many non-pharmacological treatments for chronic non-malignant pain, anxiety and insomnia, such as cognitive behavioural therapy (CBT) and physiotherapy can be expensive for patients and difficult to access. Opioid and benzodiazepine medications are PBS subsidised, further increasing the gap between the cost of pharmacological and non-pharmacological treatments and making it more likely that pharmacological based treatments will be prescribed and used.

Moreover, not all effective medications are subsidised by the PBS. Several non-opioid medicines used in the treatment of pain are not approved for subsidy by the PBS for that purpose. In order to use them, patients are required to pay their full unsubsidised cost, making them substantially more expensive than PBS-subsidised opioids, which discourages their use.

Additionally, Medicare Australia's remuneration practices appear to favour shorter consultations. This makes it difficult for prescribers to allocate sufficient time to conduct comprehensive assessments, to manage patients with complex needs in relation to their medicine use and to coordinate multi-disciplinary care.

There are also long waiting periods for patients to access specialist multidisciplinary pain services, particularly in the public sector. Likewise patients experiencing difficulties with anxiety, insomnia or alcohol and other drug (including prescription drug) use can also have difficulties accessing specialist services. Prominent among these are the difficulties associated with accessing opioid substitution therapy (OST).

Problems can also arise with the links between in-patient hospital care and community-based care. This can result in the continued use of discharge medications long after they have ceased to be clinically indicated.

All these systemic factors occur against a background of Australian cultural beliefs that a visit to a doctor should result in a prescription and that 'there is a pill to cure all ills'. Patients increasingly present to prescribers requesting predetermined medication treatment regimes. This can make it difficult for prescribers to suggest alternative therapies.

There is also emerging evidence that problems associated with the poor quality use of these pharmaceuticals do not impact equally on all Australian consumers. In particular, socially disadvantaged Australians and those living in rural and remote regions appear to be most severely impacted. This reflects complex inter-relationships between socio-economic background, health status and levels of access to services.

Social determinants are very important... we note the majority of our referral to persistent pain services in the public sector arise from the areas of greatest socioeconomic disadvantage. This may be different in the private sector but we don't get to see across those boundaries
(Submission to the National Pharmaceutical Drug Misuse Framework for Action).

Knowledge gaps

There is a range of gaps in our knowledge about the extent and nature of misuse and poor quality use of medications in Australia.

Relatively little research has been conducted into this issue and research that has been conducted has been of limited scope. In addition, mechanisms are not well developed to either coordinate pharmaceutical drug-related data or to monitor the level of harms. The needs of those requiring treatment for pharmaceutical drug problems are also not well understood.

Problems with current regulation and monitoring systems also result in knowledge gaps. Not all existing monitoring systems cover relevant prescription drugs in a consistent manner. The systems cannot track medications to the individual patient and/or cannot do so in a timely way. Under the current systems, fraudulent presentations for opioid prescriptions are difficult to identify, as are people who are engaged in prescription shopping for the purpose of supplying pharmaceuticals for profit. As a result, the extent of these problems is largely unknown.

Information is also held by different agencies (such as health and law enforcement agencies) and different jurisdictions and is not always merged to form a comprehensive picture of utilisation patterns and problems. Police, for example, have no interest in accessing information on most individuals' medication usage patterns and only become involved in this issue when there is strong evidence of criminal activity, such as trafficking. Nevertheless, police currently do not have access to the data they require to effectively respond to these crimes which limits their capacity to reduce the harm associated with these medications.

APPENDIX II: Links to other strategies

This Framework was prepared in the context of, and supports the directions of, a range of other national strategies. The table below highlights the linkages between each of the actions under this Framework and relevant parts of other strategies.

National Pharmaceutical Drug Misuse Framework for Action: Links with other Strategies				
National Pharmaceutical Drug Misuse Framework for Action	National Drug Strategy	National Strategy for the Quality Use of Medicines	National Pain Strategy	National Mental Health Plan
1.1 Progress implementation of the nationally-based and jurisdictionally consistent Electronic Recording and Reporting of Controlled Drugs (ERRCD) system which enables prescribers, dispensers and regulators to have real time online access to information concerning patients' access to prescription opioids and other Schedule 8 medicines.	Pillar 2:- Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).	Objective 1: Improve QUM by healthcare consumers; and Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.	Goal 5: Quality improvement and evaluation, Objective 17 (Ensure quality use of medicines for pain management in the community and improve systems to detect and manage unsanctioned use).	
1.2 Consider future enhancements to the ERRCD system to meet the characteristics of a comprehensive coordinated medication management system.	Pillar 2:- Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).	Objective 1: Improve QUM by healthcare consumers; and Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.	Goal 5: Quality improvement and evaluation, Objective 17 (Ensure quality use of medicines for pain management in the community and improve systems to detect and manage unsanctioned use).	
1.3 Where necessary, enhance the required regulatory infrastructure to respond to ERRCD-generated data.	Pillar 2: - Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).	Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.	Goal 5:- Quality improvement and evaluation, Objective 17 (Ensure quality use of medicines for pain management in the community and improve systems to detect and manage unsanctioned use).	
1.4 Coordinate national education about the ERRCD system for health and welfare professionals and the broader community.	Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).	Objective 1: Improve QUM by healthcare consumers; and Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.	Goal 2: Knowledgeable, empowered and supported consumers, Objective 5 (Improve community understanding of the nature of chronic pain and best practice management) Goal 5: Quality improvement and evaluation, Objective 17 (Ensure quality use of medicines for pain management in the community and improve systems to detect and manage unsanctioned use).	

National Pharmaceutical Drug Misuse Framework for Action	National Drug Strategy	National Strategy for the Quality Use of Medicines	National Pain Strategy	National Mental Health Plan
<p>2.1 Develop and/or promote national guidelines for the (non-pharmacological and pharmacological) treatment of conditions commonly implicated in the problematic use of these pharmaceuticals including:</p> <ul style="list-style-type: none"> • Pain (acute, chronic non-malignant and cancer); • Mental health problems (e.g. anxiety); • Sleep disorders; and • Alcohol and other drug use problems (including pharmacotherapy). 	<p>Pillar 1: Demand Reduction Objective 2 - Reduce use of drugs in the community Objective 3 - Support people to recover from dependence and reconnect with the community Pillar 2: Supply Reduction Objective 2 - Control and manage the supply of alcohol, tobacco and other legal drugs Supporting Approaches - Commitment to evidence</p>	<p>Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators</p>	<p>Goal 3: Skilled professionals and best practice evidence based care Objective 10 - Establish and promote systems and guidelines to ensure adequate management of acute, chronic and cancer pain Goal 5: Quality improvement and evaluation Objective 17 - Ensure quality use of medicines for pain management in the community and improve systems to detect and manage unsanctioned use Objective 18 - Improve standards in pain management by developing national benchmarking of outcomes</p>	<p>Policy direction 4: Early intervention Policy direction 5: Access to the right care at the right time Policy direction 9: Quality and outcomes Policy direction 10: Building and using the evidence base</p>
<p>2.2 Explore options to enhance peer review mechanisms, practice enhancement approaches and disciplinary measures for prescribers who consistently and inappropriately prescribe outside the boundaries of the proposed guidelines.</p>	<p>Supporting approaches: Workforce – Commitment to workforce development</p>	<p>Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.</p>	<p>Goal 3: Skilled professionals and best practice evidence based care. Objective 9 (Train and support health practitioners in best-practice pain assessment and management) and Objective 10 (Establish and promote systems and guidelines to ensure adequate management of acute, chronic and cancer pain).</p>	
<p>2.3 Enhance undergraduate, postgraduate and in-service education programs for the medical, health and human services workforces about the quality management of problems such as pain, mental health problems, sleep disorders and alcohol and other drug problems .</p>	<p>Supporting approaches : Workforce – Commitment to workforce development.</p>	<p>Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.</p>	<p>Goal 3: Skilled professionals and best practice evidence based care. Objective 9 (Train and support health practitioners in best-practice pain assessment and management) and Objective 10 (Establish and promote systems and guidelines to ensure adequate management of acute, chronic and cancer pain).</p>	<p>Policy direction 8: (Workforce).</p>

National Pharmaceutical Drug Misuse Framework for Action	National Drug Strategy	National Strategy for the Quality Use of Medicines	National Pain Strategy	National Mental Health Plan
<p>2.4 Identify opportunities to better support prescribers who feel pressured by patients to provide medications inappropriately.</p>	<p>Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).</p>	<p>Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.</p>	<p>Goal 3: Skilled professionals and best practice evidence based care, Objective 9 (Train and support health practitioners in best-practice pain assessment and management).</p>	
<p>3.1 Explore opportunities to enhance the contribution that pharmacists can make to the care plans of patients.</p>	<p>Supporting approaches: Workforce – Commitment to workforce development.</p>	<p>Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.</p>	<p>Goal 3: Skilled professionals and best practice evidence based care, Objective 9 (Train and support health practitioners in best-practice pain assessment and management) and Goal 4: Access to interdisciplinary care at all levels, Objective 12 (Develop and evaluate patient-centred service delivery in the community which provide interdisciplinary assessment, care and support as part of comprehensive primary health care centres and services).</p>	<p>Policy direction 8: (Workforce).</p>
<p>3.2 Review and, where necessary, enhance protocols for pharmacists concerning acceptable practice in the dispensing of these medications.</p>	<p>Supporting approaches : Workforce – Commitment to workforce development.</p>	<p>Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.</p>	<p>Goal 3: Skilled professionals and best practice evidence based care, Objective 9 (Train and support health practitioners in best-practice pain assessment and management).</p>	<p>Policy direction 8: (Workforce).</p>
<p>3.3 Investigate options to improve access to undergraduate and in-service professional development programs for pharmacists to better utilise their professional abilities to enhance the quality use of these medications.</p>	<p>Supporting approaches : Workforce – Commitment to workforce development.</p>	<p>Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.</p>	<p>Goal 3: Skilled professionals and best practice evidence based care, Objective 9 (Train and support health practitioners in best-practice pain assessment and management).</p>	<p>Policy direction 8 (Workforce).</p>

National Pharmaceutical Drug Misuse Framework for Action	National Drug Strategy	National Strategy for the Quality Use of Medicines	National Pain Strategy	National Mental Health Plan
<p>3.4 Investigate options to establish or enhance peer review mechanisms and practice enhancement measures for pharmacists who dispense outside of protocol boundaries.</p>	<p>Supporting approaches: Workforce – Commitment to workforce development.</p>	<p>Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.</p>	<p>Goal 3: Skilled professionals and best practice evidence based care, Objective 9 (Train and support health practitioners in best-practice pain assessment and management) and Objective 10 (Establish and promote systems and guidelines to ensure adequate management of acute, chronic and cancer pain). Goal 5: Quality improvement and evaluation, Objective 17 (Ensure quality use of medicines for pain management in the community and improve systems to detect and manage un sanctioned use).</p>	
<p>3.5 Enhance the current pharmacy staged supply arrangements.</p>	<p>Pillar 1: Demand Reduction – Objective 3, (Support people to recover from dependence and reconnect with the community); and Pillar 2: Supply reduction – Objective 2, (Control and manage the supply of alcohol, tobacco and other legal drugs).</p>		<p>Goal 3: Objective 10 (Establish and promote systems and guidelines to ensure adequate management of acute, chronic and cancer pain).</p>	

National Pharmaceutical Drug Misuse Framework for Action	National Drug Strategy	National Strategy for the Quality Use of Medicines	National Pain Strategy	National Mental Health Plan
<p>3.6 Enhance the quality use of medicines in residential aged care facilities.</p>	<p>Supporting approaches : Workforce – Commitment to workforce development</p>	<p>Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators</p>	<p>Goal 5: Quality improvement and evaluation, Objective 20 (Improve standards in pain management services and residential aged care facilities by developing ongoing quality improvement systems).</p>	
<p>3.7 Enhance the awareness of a range of health and welfare professions regarding effective treatments for:</p> <ul style="list-style-type: none"> • Pain (acute, chronic non-malignant and cancer); • Mental health problems (e.g. anxiety); • Sleep disorders; and • Alcohol and other drug use problems (including pharmacotherapy). 	<p>Pillar 1: Demand Reduction – Objective 3, (Support people to recover from dependence and reconnect with the community); and Supporting approaches – Workforce – Commitment to workforce development.</p>		<p>Goal 3: Skilled professionals and best practice evidence based care, Objective 9 (Train and support health practitioners in best-practice pain assessment and management).</p>	<p>Policy direction 8: (Workforce); and Policy direction 2.5 (Access to the right care at the right time).</p>

National Pharmaceutical Drug Misuse Framework for Action	National Drug Strategy	National Strategy for the Quality Use of Medicines	National Pain Strategy	National Mental Health Plan
<p>4.1 Evaluate the extent to which different jurisdictional regulatory models impact on the misuse of these drugs and identify standardisation benchmarks for good practice.</p>	<p>Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).</p>		<p>Goal 5: Quality improvement and evaluation, Objective 17 (Ensure quality use of medicines for pain management in the community and improve systems to detect and manage unsanctioned use).</p>	
<p>4.2 Provide this Framework to the delegate of the Secretary of the Department of Health and Ageing for consideration in determining the need for a review of the scheduling of opioids and benzodiazepines.</p>	<p>Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).</p>		<p>Goal 5: Quality improvement and evaluation, Objective 17 (Ensure quality use of medicines for pain management in the community and improve systems to detect and manage unsanctioned use).</p>	
<p>4.3 Explore options to enhance the information sharing capacities of law enforcement and health agencies to reduce opportunities for theft, diversion, trafficking and fraud in pharmaceutical drugs.</p>	<p>Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).</p>		<p>Goal 5: Quality improvement and evaluation, Objective 17 (Ensure quality use of medicines for pain management in the community and improve systems to detect and manage unsanctioned use).</p>	
<p>4.4 Monitor and respond to emerging trends in local and international internet pharmacies.</p>	<p>Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).</p>		<p>Goal 5: Quality improvement and evaluation, Objective 17 (Ensure quality use of medicines for pain management in the community and improve systems to detect and manage unsanctioned use).</p>	
<p>4.5 Consider the deliberations of the Working Group on the Promotion of Therapeutic Products regarding strengthening the self regulatory framework governing the relationship between health care professionals and therapeutic goods companies.</p>	<p>Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).</p>	<p>Objective 3: Gain the commitment of the medicines industry (to the quality use of medicines).</p>		
<p>4.6 Assess the feasibility of removing opioid and benzodiazepine medications from advertising in pharmacy price lists.</p>	<p>Pillar 1: Demand reduction, Objective 2 (Reduce the use of drugs in the community); and Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).</p>			
<p>National Pharmaceutical Drug Misuse Framework for Action</p>	<p>National Drug Strategy</p>	<p>National Strategy for the Quality Use of Medicines</p>	<p>National Pain Strategy</p>	<p>National Mental Health Plan</p>

<p>4.7 Encourage the Pharmaceutical Benefits Advisory Committee and the Therapeutic Goods Administration to increase the emphasis placed on the harms associated with pharmaceutical drug misuse in their deliberations.</p>	<p>Pillar 1: Demand reduction, Objective 2 (Reduce the use of drugs in the community); and Pillar 3: Harm reduction, Objective 3 (Reduce harms to individuals)</p>			
<p>4.8 Explore opportunities to ensure that the enhanced monitoring and regulation of medications intended for human consumption does not enhance diversion from veterinary supplies.</p>	<p>Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).</p>			

National Pharmaceutical Drug Misuse Framework for Action	National Drug Strategy	National Strategy for the Quality Use of Medicines	National Pain Strategy	National Mental Health Plan
<p>5.1 Explore opportunities to improve access to treatments and services.</p>	<p>Pillar 1: Demand reduction, Objective 2 (Reduce the use of drugs in the community) and Objective 3 (Support people to recover from dependence and reconnect with the community); Pillar 3: Harm reduction, Objective 3 (Reduce harms to individuals); Supporting approach 1: (Workforce); and Supporting approach 2: (Commitment to evidence).</p>	<p>Objective 1: Improve QUM by healthcare consumers; and Objective 2: Improve the quality use of medicines by healthcare providers and health educators.</p>	<p>Goal 4: Access to interdisciplinary care at all levels, Objective 12 (Develop and evaluate patient-centred service delivery and funding models for pain management in the community which provide interdisciplinary assessment, care and support as part of comprehensive primary health care centres and services), Objective 14 (Expedite access to tier 1 multidisciplinary pain clinics for people with more complex problems) and Objective 15 (Ensure tertiary specialist pain clinics have resources needed to support key strategies). Goal 5: Quality improvement and evaluation, Objective 19 (Ensure equity of access and appropriate use of non-pharmaceutical interventions).</p>	<p>Policy direction 8: (Workforce); and Policy direction 2.5 (Access to the right care at the right time).</p>
<p>5.2 Explore opportunities to enhance liaison in transitional medication management between hospitals and community settings.</p>	<p>Pillar 1: Demand reduction, Objective 2 (Reduce the use of drugs in the community); and Supporting approach 1 (Workforce).</p>	<p>Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.</p>	<p>Goal 3: Skilled professionals and best practice evidence based care, Objective 9 (Train and support health practitioners in best-practice pain assessment and management).</p>	
<p>5.3 Where possible enhance the range of medication pack sizes and/or dispensing options for Pharmaceutical Benefits Scheme medications.</p>	<p>Pillar 1: Demand reduction, Objective 2 (Reduce the use of drugs in the community).</p>		<p>Goal 3: Skilled professionals and best practice evidence based care, Objective 10 (Establish and promote systems and guidelines to ensure adequate management of acute, chronic and cancer pain).</p>	

National Pharmaceutical Drug Misuse Framework For Action	National Drug Strategy	National Strategy for the Quality Use of Medicines	National Pain Strategy	National Mental Health Plan
<p>5.4 Promote utilisation by prescribers of Medicare Benefits Schedule items which remunerate and target medication review and/or non-pharmacological management of conditions such as pain and mental illness.</p>	<p>Supporting approach 1: (Workforce).</p>	<p>Objective 2: Improve the quality use of medicines by health practitioners, healthcare providers and health educators.</p>	<p>Goal 4: Access to interdisciplinary care at all levels, Objective 12 (Develop and evaluate patient-centred service delivery and funding models for pain management in the community which provide interdisciplinary assessment, care and support as part of comprehensive primary health care centres and services).</p>	
<p>6.1 Widen the acceptability of non-drug and non-opioid, non-benzodiazepine treatments for physical and psychological problems.</p>	<p>Pillar 1:- Demand reduction, Objective 1 (Prevent uptake and delay onset of drug use) and Objective 2 (Reduce the use of drugs in the community).</p>	<p>Objective 1: Improve quality use of medicines by healthcare consumers.</p>	<p>Goal 2: Knowledgeable , empowered and supported consumers, Objective 5 (Improve community understanding of the nature of chronic pain and best practice management) and Objective 6 (Provide easily accessible information to assist people with pain, careers and other supporters, and practitioners to understand and be more involved in managing pain).</p>	<p>Policy direction 2.5: (Access to the right care at the right time).</p>
<p>6.2 Enhance the accessibility of information available to consumers regarding the potential harms associated with opioids and benzodiazepines.</p>	<p>Pillar 1: Demand reduction, Objective 2 (Reduce the use of drugs in the community).</p>	<p>Objective 1: Improve QUM by healthcare consumers.</p>	<p>Goal 2: Knowledgeable , empowered and supported consumers, Objective 5 (Improve community understanding of the nature of chronic pain and best practice management) and Objective 6 (Provide easily accessible information to assist people with pain, careers and other supporters, and practitioners to understand and be more involved in managing pain).</p>	
<p>6.3 Further standardise the labelling of medicines in Australia.</p>	<p>Pillar 1: Demand reduction, Objective 2 (Reduce the use of drugs in the community); and Pillar 3 – Harm reduction, Objective 3 (Reduce harms to individuals).</p>	<p>Objective 1: Improve QUM by healthcare consumers.</p>	<p>Goal 2: Knowledgeable , empowered and supported consumers, Objective 6 (Provide easily accessible information to assist people with pain, careers and other supporters, and practitioners to understand and be more involved in managing pain).</p>	

National Pharmaceutical Drug Misuse Framework for Action	National Drug Strategy	National Strategy for the Quality Use of Medicines	National Pain Strategy	National Mental Health Plan
<p>6.4 Promote the availability of review and appeal processes for patients and their prescribers who believe that access to target medications has been unfairly denied by enhanced monitoring and regulation.</p>				
<p>7.1 If necessary re-orientate existing services or develop new programs to address the needs of the clients experiencing difficulties with problematic pharmaceutical use including both those who do, and those who do not, have a history of illicit drug use.</p>	<p>Pillar 1: Demand reduction, Objective 2 (Reduce the use of drugs in the community); Pillar 3: Harm reduction, Objective 3 (Reduce harms to individuals); Supporting approaches 1 (Workforce); and Supporting approaches 2 (Commitment to evidence).</p>	<p>Objective 1: Improve quality use of medicines by healthcare consumers; and Objective 2: Improve the quality use of medicines by health practitioners, health care providers and health educators.</p>	<p>Goal 3: Skilled professionals and evidence-based care, Objective 10 (Establish and promote systems and guidelines to ensure adequate management of acute, chronic and cancer pain).</p>	<p>Policy direction 2.5: (Access to the right care at the right time).</p>
<p>7.2 Enhance the capacity of treatment services to meet the needs of ageing populations who have had longer-term exposure to pharmaceutical and non-pharmaceutical opioids.</p>	<p>Pillar 1: Demand reduction, Objective 2 (Reduce the use of drugs in the community); Pillar 3: Harm reduction, Objective 3 (Reduce harms to individuals); Supporting approaches 1: (Workforce); and Supporting approaches 2: (Commitment to evidence).</p>		<p>Goal 3: Skilled professionals and evidence-based care, Objective 10 (Establish and promote systems and guidelines to ensure adequate management of acute, chronic and cancer pain).</p>	
<p>7.3 Enhance access to options available for police and courts to divert offenders involved in the problematic use of these medications away from the criminal justice system.</p>	<p>Pillar 1: Demand reduction, Objective 2 (Reduce the use of drugs in the community).</p>			
<p>7.4 Ensure that Australia's needle and syringe programs have the ability to respond to the trend towards the misuse of pharmaceutical medications by injection.</p>	<p>Pillar 3: Harm reduction, Objective 3 (Reduce harms to individuals); Supporting approaches 1: (Workforce); and Supporting approaches 2: (Commitment to evidence).</p>			

National Pharmaceutical Drug Misuse Framework for Action	National Drug Strategy	National Strategy for the Quality Use of Medicines	National Pain Strategy	National Mental Health Plan
7.5 Better disseminate information concerning the potential harms and evidence-informed harm reduction measures to those involved, or potentially involved in the problematic use of these pharmaceuticals.	Pillar 3: Harm reduction, Objective 3 (Reduce harms to individuals).		Goal 2: Knowledgeable, empowered and supported consumers, Objective 6 (Provide easily accessible information to assist people with pain, careers and other supporters, and practitioners to understand and be more involved in managing pain).	
7.6 Explore opportunities to expand NSPs into rural areas to a larger extent than is currently the case.	Pillar 3: Harm reduction, Objective 3 (Reduce harms to individuals).			

National Pharmaceutical Drug Misuse Framework for Action	National Drug Strategy	National Strategy for the Quality Use of Medicines	National Pain Strategy	National Mental Health Plan
8.1 Promote the use of tamper-resistant technologies for target medications.	Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).	Objective 3: Gain the commitment of the medicines industry to the quality use of medicines.		
8.2 Consider the feasibility of implementing pharmaceutical pedigrees.	Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).	Objective 3: Gain the commitment of the medicines industry to the quality use of medicines.	Goal 5: Quality improvement and evaluation, Objective 5 (Ensure quality use of medicines for pain management and improve systems to detect and manage unsanctioned use).	
8.3 Enhance the use of electronic prescriptions to minimise the risk of dispensing errors and fraudulent alteration of prescriptions.	Pillar 2: Supply Reduction, Objective 2 (Control and Manage the supply of alcohol, tobacco and other legal drugs).		Goal 5: Quality improvement and evaluation, Objective 5 (Ensure quality use of medicines for pain management and improve systems to detect and manage unsanctioned use).	
9.1 Enhance and better co-ordinate pharmaceutical-related data collection and sharing processes to provide a more holistic picture of patterns of the prescription and utilisation as well as profiles and levels of harm.	Supporting approaches 2: (Commitment to evidence).		Goal 6: Research, Objective 22 (Enable pain research at a national level), Objective 23 (Identify information gaps underpinning all objectives in the NPS) and Objective 24 (Ensure research is relevant to populations with special needs).	Policy direction 10: (Building and using the evidence base).
9.2 Conduct a range of specific research activities to focus on areas that could better inform public policy in this area.	Supporting approaches 2: (Commitment to evidence).		Goal 6: Research, Objective 22 (Enable pain research at a national level), Objective 23: (Identify information gaps underpinning all objectives in the NPS) and Objective 24 (Ensure research is relevant to populations with special needs).	Policy direction 10: (Building and using the evidence base).
9.3 Develop an action research based methodology to assess the intended and unintended outcomes of the implementation of this Framework.	Supporting approaches 2: (Commitment to evidence); and Supporting approaches 3: (performance measures).		Goal 5: Quality improvement and evaluation, Objective 18 (Improve standards in pain management by developing national benchmarking of outcomes); and Goal 6: Research, Objective 22 (Enable pain research at a national level), Objective 23 (Identify information gaps underpinning all objectives in the NPS) and Objective 24 (Ensure research is relevant to populations with special needs).	Policy direction 10: (Building and using the evidence base).

APPENDIX III: Abbreviations

AIHW	Australian Institute of Health and Welfare
ADF	Abuse Deterrent Formulations
AGREE	Appraisal of Guidelines, Research and Evaluation
ANZCA	Australian and New Zealand College of Anaesthetists
APAC	Australian Pharmaceutical Advisory Council
ARF	Abuse Resistant Formulations
CASA	Center for Addiction and Substance Abuse
CAMH	Centre for Addiction and Mental Health
CBT	Cognitive Behavioural Therapy
DCPC	Drugs and Crime Prevention Committee of the Parliament of Victoria
DORA	Drugs and Poisons Information System online Remote Access (Tasmania)
DoHA	Australian Government Department of Health and Ageing
DOHDA	Department of Health [England] and the Devolved Administrations
GP	General Practitioner
IGCD	Inter-Governmental Committee on Drugs
MCDS	Ministerial Council on Drug Strategy
MSIC	Medically Supervised Injection Centre
NPDMFA	National Pharmaceutical Drug Misuse Framework for Action
NSP	Needle and Syringe Program
NSQUM	National Strategy for the Quality Use of Medicines
OST	Opioid Substitution Therapy
PBS	Pharmaceutical Benefits Scheme
PCEHR	Personally Controlled Electronic Health Record
PDM	Pharmaceutical Drug Misuse
QUM	Quality Use of Medicines
RACP	Royal Australasian College of Physicians
RFID	Radio Frequency Identification
RPBS	Repatriation Pharmaceutical Benefits Scheme
SAMHSA	Substance Abuse and Mental Health Service Administration
SIGN	Scottish Intercollegiate Guidelines Network

APPENDIX IV: Glossary of Medicines

Alprazolam	Benzodiazepine used to treat anxiety, anxiety associated with depression, panic attacks and phobias
Benzodiazepines	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 and opioid dependence
Codeine	Opioid analgesic used to treat moderate to severe pain
Diazepam	Benzodiazepine used to treat anxiety, acute alcohol withdrawal, muscle spasm and spasticity
Fentanyl	Opioid analgesic used to treat chronic breakthrough pain, commonly used in cancer patients, post operatively and also for short duration analgesia in anaesthesia
Gabapentin	Anticonvulsant, but also an adjuvant medication used in pain treatment
Ibuprofen	Non steroidal anti-inflammatory drug
Kapanol	Controlled release morphine
Methadone	Synthetic opioid analgesic used to treat opioid dependence and severe pain
Mirtazepine	A tetracyclic anti-depressant
Morphine	Opioid analgesic used to treat severe pain
Opioid	A scientific term that refers to both natural and synthetic drugs whose effects are mediated by specific receptors in the central and peripheral nervous systems commonly used in pain relief
Oxazepam	Benzodiazepine used to treat anxiety and anxiety associated with depression
Oxycodone	Opioid analgesic used to treat moderate to severe pain
Pethidine	Opioid analgesic used to treat moderate to severe pain
Temazepam	Benzodiazepine used to treat insomnia
Zolpidem	Non-benzodiazepine used to treat insomnia
Zopiclone	Non-benzodiazepine used to treat insomnia

APPENDIX V: 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.

Anxiolytic medications are used for the treatment of anxiety.

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.

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.

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.

Larger bore barrelled syringes are syringes with a larger diameter bore and are more commonly used to inject pharmaceutical drugs.

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.

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.

Pharmaceutical pedigree is an audit trail that follows a drug from the time it is manufactured through the distribution system to a pharmacy.

A psychoactive drug is a chemical substance the use of which results in changes in perception, mood, consciousness, cognition or behavior.

Schedule 3 (S3) medicines do not require a prescription and are only available for sale from pharmacies. They also require a pharmacist to provide advice and counselling on dispensing.

Schedule 4 (S4) medicines require a prescription, but are not controlled drugs.

Schedule 8 (S8) drugs and poisons, otherwise known as controlled drugs, are substances and preparations for therapeutic use which have high potential for misuse and dependence.

Syringe-driven filters make it possible to filter material that is to be injected. A syringe is attached to the filter which is used to force the liquid drug through the filtering media. Large particles are retained in the filtering media.

Winged infusion sets (or butterfly needles) are used for intravenous injection. The needle that is inserted into the vein is stabilised by an attached piece of plastic shaped like butterfly wings. The needle is attached to a flexible tube into which the drug is injected.

Z-drugs are a group of non-benzodiazepine drugs with effects similar to benzodiazepines which are used in the treatment of insomnia. They are called Z-drugs because most have names starting with the letter 'Z'.

References

- ABCI. (2000). *Australian illicit drug report, 1998-99*. Canberra: ABCI.
- Australian Bureau of Statistics. (1992) *Australian demographic statistics December 1991*. Retrieved 21 January 2012 from: <http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/3101.0Dec%201991?OpenDocument>
- Australian Bureau of Statistics. (2011) *Australian demographic statistics December 2010*. Retrieved 21 January 2012 from: <http://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/3101.0Main+Features1Dec%202010>
- ACC. (2011). *Illicit drug data report, 2009-10*. Canberra: ACC.
- AIHW. (n.d.). *National hospital morbidity database*. Retrieved 18 October 2009, from <http://d01.aihw.gov.au/cognos/cgi-bin/ppdscgi.exe?DC=Q&E=/AHS/pdx0708>
- ANZCA. (2010). *National pain strategy: pain management for all Australians*. St Kilda, VIC: Australian and New Zealand College of Anaesthetists, Faculty of Pain Medicine, Australian Pain Society, Chronic Pain Australia.
- APAC. (2005). *Guiding principles to achieve continuity in medication management*. Canberra: Australian Pharmaceutical Advisory Council, Commonwealth of Australia.
- 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).
- Centers for Disease Control and Prevention. (2010). Number of poisoning deaths involving opioid analgesics and other drugs or substances, United States, 1999–2007. *Morbidity and Mortality Weekly Report*. 59, 32.
- Collins, D., & Lapsley, H. (2008). *The costs of tobacco, alcohol and illicit drug abuse to Australian society in 2004/05*. Canberra: Commonwealth of Australia.
- Commonwealth of Australia. (1999). *National medicines policy 2000*. Canberra: Department of Health and Ageing, Commonwealth of Australia.
- Commonwealth of Australia. (2002). *National strategy for the quality use of medicines*. Canberra: Commonwealth of Australia.
- Commonwealth of Australia. (2010). *National needle and syringe programs strategic framework 2010-2014*. Canberra: Commonwealth of Australia.
- Commonwealth of Australia. (2011). *Improving primary health care for all Australians*. Canberra: Commonwealth of Australia.
- Darke, S., Dufflou, J., & Torok, M. (2011). Toxicology and characteristics of fatal oxycodone toxicity cases in New South Wales, Australia 1999-2008. *Forensic Sciences*, 56, 3, 690-693.
- 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 pharmaceutical drugs in Victoria: Final report*. Melbourne: Drugs and Crime Prevention Committee, Parliament of Victoria.
- Dhalla, I, Mamdani, M., Sivilotti, M., Kopp, A., Kopp, A., Qureshi, O., Juurlink, D. (2009). Prescribing of opioid analgesics and related mortality before and after the introduction of long-acting oxycodone. *Canadian Medical Association Journal*. 181(12), 891-896.
- 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. (personal communication, February 21, 2011).
- DOHDA. (2007). *Drug misuse and dependence: UK guidelines on clinical management*. London: Department of Health (England), the Scottish Government, Welsh Assembly and Northern Ireland Executive.

- Elliott, R., (2006). Problems with medication use in the elderly: An Australian Perspective. *Journal of Pharmacy Practice and Research* 36, 1, 58-66.
- 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.
- Hansen, R, Oster, G., Edelsberg, J., Woody, G., & Sullivan, S. (2011). Economic costs of non-medical use of prescription opioids. *Clinical Journal of Pain*, 27, 3. 194-202.
- Hollingworth, S., & Siskind, D. (2010). Anxiolytic, hypnotic and sedative medication use in Australia. *Pharmacoepidemiology and Drug Safety*, 19. 280–288
- INCB. (2010). *Report on the International Narcotics Control Board for 2010*. Vienna: United Nations, International Narcotics Control Board.
- Magin, P., Adams, J., Sibbritt, D. W., Joy, E., & Ireland, M. C. (2005). Experiences of occupational violence in Australia urban general practice: A cross-sectional study of GPs. *Medical Journal of Australia*, 183(7), 352-356.
- MSIC. (2010). *Face up*. Sydney: Medically Supervised Injecting Centre, Uniting Care.
- Nielsen, S., Bruno, R., Carruthers, S., Fischer, J., Lintzeris, N., & Stooove, M. (2008). *Investigation of pharmaceutical misuse amongst drug treatment clinics: Final report 2008*. Melbourne: Turning Point Alcohol & Drug Centre.
- Nielsen, S., Dietze, P., Lee, N., Dunlop, A., & Taylor, D. (2007). Concurrent buprenorphine and benzodiazepines use and self-reported opioid toxicity in opioid substitution treatment. *Addiction*, 102(4), 616-622.
- NPS. (2010). *NPS prescribing practice review 49: Management options for improving sleep*. Retrieved 14 January 2011, from http://www.nps.org.au/health_professionals/publications/prescribing_practice_review/current/prescribing_practice_review_49
- PBS (n.d.). *Expenditure and Prescriptions Twelve Months to 30 June 2010*. Canberra: PBS.
- RACP. (2009). *Prescription opioid policy: Improving management of chronic non-malignant pain and prevention of problems associated with prescription opioid use*. Sydney: The Royal Australasian College of Physicians.
- Rintoul, A., Dobbin, M., Drummer, O., & Ozanne-Smith, J. (2010). Increasing deaths involving oxycodone, Victoria, Australia, 2000-09. *Injury Prevention, Advanced Online Publication*.
- Roberts MS, King M, Stokes JA, Lynne TA, Bonner CJ, McCarthy S, et al. (1998) Medication prescribing and administration in nursing homes. *Age and Aging*, 27, 385-92.
- Roche, A., & Pidd, K. (2010). *Alcohol and other Drugs Workforce Development Issues and Imperatives. Setting the Scene*. Adelaide: National Centre for Education and Training on Addiction, Flinders University.
- Roxburgh, A., Bruno, R., Larance, B., & Burns, L. (2011). Prescription of opioid analgesics and related harms in Australia. *Medical Journal of Australia*, 195, 5, 280-284.
- Stafford, J., & Burns, L. (2011). *Australian drug trends, 2010. Findings from the illicit drug reporting system (IDRS). Australian drug trends series No. 55*. Sydney: National Drug and Alcohol Research Centre, University of NSW.
- Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (2010). *The DAWN Report: Highlights of the 2009 drug abuse warning network (DAWN): Findings on drug-related emergency department visits*. Rockville, MD.
- US Pharmacopeia. (2011). *About USP*. Retrieved 2 January 2011, from <http://www.usp.org/aboutUSP/>
- Wares, M. (2007). *Prescription Shopping Program*. Presentation given at the National Pharmaceutical Drug Misuse Workshop, Melbourne.
- Woods, J., Gerostamoulos, D., & Drummer, O. (2009). *Heroin deaths in Victoria 2007-08*. Melbourne: Victorian Institute of Forensic Medicine, Department of Forensic Medicine, Monash University.