Policy Paper



Pharmaceuticals

May 2010

Executive Summary

Prescription and over-the-counter medicines have made a significant and positive contribution to the health and wellbeing of Australians. Generally, health practitioners and pharmacists prescribe and supply medicines in an informed and appropriate manner. In turn, most consumers take them responsibly and their health outcomes are improved. However, nearly all medicines have the potential to cause harm and when they are misused, the consequences can be dangerous and even fatal.

This paper addresses misuse, defined as "use by individuals that occurs without a prescription, or other than intended by the prescriber". In the instance of over the counter purchase, misuse is defined as "use other than for the instructions on the label or the intended purpose" (Nielsen et al., 2008a). This paper further focuses on those medicines which have been identified as particularly susceptible to misuse, dependence, and subsequent harm: benzodiazepines, opioid analgesics, and stimulants.

People that deliberately misuse prescription and over-the-counter drugs may do so for a number of reasons. They may wish to become intoxicated or to ameliorate the effects of withdrawal from illicit drugs. Others may use prescription and over-the-counter drugs when they are unable to obtain their illicit drug of choice. Some may have developed dependence following therapeutic use.

There is a need to research and create a greater awareness of the issues, problems, and possible solutions regarding the misuse of prescribed and over-the-counter medicines. We must encourage good prescribing and dispensing practices and address any reluctance by practitioners to discuss the issue of misuse and the risk of addition to pharmaceuticals with their patients. We must also ensure that appropriate treatments are available for those individuals who seek to address their misuse of prescription and over-the-counter medications.

Background

There are many problems associated with the misuse of pharmaceutical drugs. They include:

- Harms relating to dependence on pharmaceuticals, in some cases where use was initiated for therapeutic use:
 - Long-term and high dose use of over the counter products containing codeine and paracetamol or ibuprofen
 - Dependence to prescription pain relievers resulting from inappropriate or poorly monitored use
- Harms from unsanctioned routes of administration, e.g. injecting-related harms from intravenous administration of products intended for oral use
- Harms related to pharmacological effects of pharmaceuticals
 - o Overdose
 - Impaired driving; and

- Disinhibition, impaired judgement, and memory loss with high potency benzodiazepines such as alprazolam (eg Xanax®)
- Mixing alcohol and prescription drugs, or mixing multiple prescription drugs to achieve and enhance intoxication

While ADCA recognises the broad range of problems related to prescription drug misuse, it does not attempt to address all of them in this paper. Rather, as noted above, this paper focuses on the misuse of benzodiazepines, opioid analgesics, and stimulants – drugs that have been shown to be especially prone to misuse.

Drug Effects

Benzodiazepines

Benzodiazepines are a group of approximately 25 specific drugs which produce a tranquillising effect by slowing down the activity of the Central Nervous System (CNS). Benzodiazepines are prescribed to relieve stress and anxiety and to treat sleep disorders and panic attacks. They are also sometimes prescribed to treat convulsive disorders such as epilepsy, to treat involuntary movement disorders and spasticity, to help withdraw from alcohol or as an anaesthetic prior to surgery (Australian Drug Foundation 2006).

In the short term, use of benzodiazepines can lead to relaxation, calmness and relief from anxiety. Higher doses can cause drowsiness, sleep, and over-sedation. They can also cause confusion, poor coordination and judgement, memory loss, blurred vision, and dizziness. The longer term use of benzodiazepines can lead to non-reversible memory loss and other impairments of cognitive functions, anxiety, and irritability, as well as headaches, weight gain and a greater risk of falls among older people. It can also lead to tolerance and psychological or physical dependence as well as withdrawal when use of the drug is reduced or ceased (Australian Drug Foundation 2006).

Analgesics

Analgesics are used for the treatment and management of pain and may be broadly grouped into opioid analgesics and simple analgesics. While simple analgesics are certainly abused by some consumers, it is the misuse of opioid analgesics which appears to result in the greatest harm. Opioid analgesics include morphine, codeine, pethidine, oxycodone, and methadone. Like benzodiazepines, opioid analgesics are CNS depressants. They can produce drowsiness and euphoria and large doses may result in respiratory depression, seizures, coma, and potentially death. Misuse may also lead to psychological and/or physical dependence and subsequent withdrawal when use of the drug is discontinued.

Some non-prescription combination analgesics contain codeine in combination with simple analgesics like paracetamol and ibuprofen. These simple analgesics when taken for long periods of time or in high doses can cause serious adverse effects on the liver and gastrointestinal tract.

Stimulants

Stimulants enhance brain activity and in turn increase alertness, attention, and energy. They may be prescribed for the treatment of conditions such as narcolepsy, obesity (for appetite suppression), and attention deficit hyperactivity disorder (ADHD). Stimulants elevate heart rate and respiration and when taken in high doses may result in feelings of hostility or agitation, tremors,



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dangerously high body temperatures and/or irregular heartbeat (National Institute on Drug Abuse 2005). The misuse of prescribed stimulants has also been linked to psychotic episodes, paranoid delusions, and hallucinations (Australian Government National Drug Strategy 2008). Some common stimulants include phenteramine, dexamphetamine, and methylphenidate.

A range of non-prescription pharmaceuticals have been associated with misuse that are outside the scope of this paper. These include

- Cough syrups
- Sedating antihistamines (e.g. Avil® and Unisom®))
- laxatives, diuretics, and diet aids

Patterns of use and other trends

Individuals may obtain prescription medicines with the intention of misuse through a variety of means, including:

- illicit market purchases
- procuring medicines from family, friends, or acquaintances.
- inappropriate prescribing
- visiting a large number of doctors (often referred to as 'doctor shopping' or 'prescription shopping')
- drug thefts; and
- forgery of prescriptions

All of these methods constitute a diversion of prescribed medicines either from the intended recipient or from appropriate use. Recent research indicates that many people do not source medications for illicit/non-medical use directly from a prescriber, with black markets and friends being common sources and theft being the source in only around 1% of cases (Nielsen et al 2008).

The National Drug Strategy Household Survey monitors the illicit/non-medical use of a number of prescribed and over-the-counter medicines. The most recent survey, which was conducted in 2007, found that the following percentages of Australians aged 14 and over reported the illicit/non medical use of a range of substances:

- 2.5% recently used pain-killers/analgesics (a reduction from 3.1% in 2001)
- 1.4% recently used tranquillisers/sleeping pills (an increase from 1.1% in 2001)

Data from the 2007 National Drug Strategy Household Survey shows 7% of Australians report lifetime use of pharmaceutical drugs for non-medical purposes, with 3.6% reporting non-medical use in the past 12 months (Australian Institute of Health and Welfare 2008). This number of people reporting recent non-medical use of pharmaceutical drugs is comparable with the numbers of people using ecstasy in Australia.

Benzodiazepines

A significant increase was seen in the non-medical use of tranquillisers and sleeping pills in persons aged 14 years and over, from 1.0% in 2004 to 1.4% in 2007 (AIHW 2008b). This represents more than a quarter of a million Australians reporting misuse of these medications (Nielsen & Lloyd, 2009).

Individuals dependent on heroin may use benzodiazepines when they are unable to obtain heroin, when they are trying to cease or reduce heroin use, to increase the effects of heroin or in relation to psychological symptoms. Research has shown that around two thirds of opioid dependents will use benzodiazepines, with approximately half of those (a third of opioid dependent people) experiencing problems with benzodiazepines (Lintzeris & Nielsen, 2009). It has also been identified that the injection of oral pharmaceutical preparations is common among injecting drug users (IDU) in Australia, particularly the combined injection of methadone syrup and benzodiazepines (Nielsen & Lloyd, 2009).

Analgesics

Analgesics are the most common group of pharmaceuticals subject to non-medical use by the Australian population, with 2.5 % of Australians reporting recent non-medical use (Australian Institute of Health and Welfare, 2008).

The majority of research available about non-medical pharmaceutical opioid use relates to particular subpopulations such as IDUs. Limited research has been conducted to understand pharmaceutical opioid dependence amongst non-IDU populations, although early work indicates there may be a considerable population of people dependent on pharmaceutical opioids that do not have an illicit substance use or treatment history (Nielsen & Cameron, 2009).

Amongst IDUs, prescription opioid use has been well documented. Data gathered as part of the 2008 Illicit Drug Reporting System (IDRS) shows that significant numbers of IDUs are engaging in the illicit use of prescription analgesics. The 2008 IDRS report indicated that:

- 73% of IDUs surveyed have ever injected morphine, up from 63% in 2001.
- 57% of IDUs surveyed have ever injected methadone, up from 42% in 2001.
- Recent use of oxycodone was reported by 30 % of the sample in 2008, up from 21% in 2005 (Stafford et al., 2009).

IDRS reports continue to note very low availability of heroin in the Northern Territory and Tasmania. The researchers suggest that this market characteristic manifests, at least partly, in high rates of non-medical use of pharmaceutical opioids in these jurisdictions. Internationally, a similar pattern of higher rates of pharmaceutical opioid misuse in isolated geographic regions has also been demonstrated (Cicero et al., 2007; Hughes, Bogdan, & Dart, 2007).

Researchers have suggested that the marked increase in the use of analgesics over the last decade may be partially attributable to an ageing population and possibly a greater propensity amongst doctors to prescribe opioid analgesics for chronic pain (Lintzeris, 2009). The complexity of managing pain and minimising risks of dependence will continue to be an important area.

Stimulants

There is a lack of data in relation to the prevalence of non-prescribed use of pharmaceutical stimulants in the general population. Among the injecting drug users interviewed in the IDRS



nationally in 2008, use and injection of pharmaceutical stimulants such as methylphenidate and dexamphetamine was relatively uncommon and infrequent, reported by 14% in the past six months prior to the survey. This was typically accessed through illicit markets rather than individuals injecting stimulants that had been prescribed to them. Of note is data that shows that the use and injection of illicitly obtained pharmaceutical stimulants in the six months preceding the survey was most common in Western Australia, Tasmania, and the Australian Capital Territory (Australian Drug Trends, 2008).

Levels of harm

It has been estimated that approximately 140 000 hospital admissions each year are associated with medication-related problems (Medicare Australia 2005).

Dependence, particularly on benzodiazepines and opioid analgesics, may occur after a relatively short period of time regardless of the original reason for treatment. Injecting of prescribed medicines designed to be taken orally such as methadone and benzodiazepines can cause severe vascular damage. In acute cases, this may result in amputation, organ damage, or stroke. Administering drugs intravenously also puts users at risk of other health problems such as the transmission of blood borne viruses, blood poisoning, and abscesses.

The use of benzodiazepines or opioid analgesics in conjunction with other Central Nervous System depressants increases the risk of overdose and may result in loss of consciousness, respiratory failure, coma, or death. Cognitive impairment and falls are other common harms associated with benzodiazepines. It has been reported that the use of antidepressant drugs in combination with benzodiazepines or opioid analgesics may also increase the risk of overdose, especially in the case of tricyclic antidepressants (National Institute on Drug Abuse 2005). Benzodiazepine use is frequently implicated in methadone and buprenorphine deaths (Lintzeris & Nielsen, 2009).

As noted above, when taken in large doses, stimulant misuse may result in feelings of hostility or agitation, tremors, dangerously high body temperatures, and/or irregular heartbeat (National Institute on Drug Abuse 2005). The misuse of prescribed stimulants has also been linked to psychotic episodes, paranoid delusions, and hallucinations (Australian Government National Drug Strategy 2008).

Harm Reduction Strategies

There are many strategies that can be used to reduce the harms arising from the misuse of prescription drugs. These include:

Prescriber initiatives

Good prescribing practice is a key strategy for reducing prescription drug misuse. Good prescribing practice involves careful and considered diagnoses, clear therapeutic goals, the use of non-drug therapies where suitable, prescribing appropriate types, formulations and amounts of medication, explaining the effects of medications and any risk of dependence, as well as implementing regular medication reviews. Using this type of universal precautions framework is an approach endorsed by experts in pain management and addiction medicine (Chou et al., 2009).



A range of non-pharmacological therapies exist that are appropriate alternatives in many cases to benzodiazepines, opioid analgesics and stimulants. These include pain and sleep clinics, counselling, behavioural therapies, relaxation techniques, and dietary and exercise programs. In some cases there may be evidence for alternative therapies such as acupuncture. For some individuals, these therapies may actually treat the underlying problem rather than simply ameliorating symptoms such as stress and sleeplessness.

Other initiatives which can be used by prescribers to minimise the harms associated with prescription drug misuse include being vigilant in identifying substance misuse or dependence, assisting the individual to recognise misuse or dependence where it exists, setting goals for recovery, and assisting the individual to seek appropriate treatment (National Institute on Drug Abuse 2005).

Pharmacists and pharmacy staff initiatives

Pharmacists may also play an important role in addressing the harm arising from prescription shopping and the misuse of prescription drugs. Pharmacists and their staff are encouraged to be aware of products that may be misused and should not supply these products where they reasonably suspect misuse. They should also be vigilant and proactive in identifying possible forged or altered prescriptions. Further, pharmacists can help to prevent prescription drug misuse by providing clear information on how a medication is to be taken, any effects the medication may have, and any possible drug interactions (National Institute on Drug Abuse 2005)

An electronic monitoring system, *Project STOP*, has been established by the Pharmacy Guild of Australia in response to concerns around pseudoephedrine misuse. Pseudoephedrine is used as a precursor for illegal manufacturing of amphetamines. *Project STOP* provides information to law enforcement as well as information to assist pharmacists to decide if a request to supply pseudoephedrine is legitimate and is applicable to prescription and over-the-counter sales. The Pharmacy Guild of Australia reported a 23% reduction in the number of clandestine methamphetamine labs detected in Queensland, where the *Project STOP* pilot program was conducted (The Pharmacy Guild of Australia, 2007).

An implementation of more detailed electronic prescription records available in real-time has been proposed. Current prescription monitoring does not include a range of non-prescription and nonsubsidised medications and its information is only available retrospectively, and as such provides limited utility for detecting problematic use at the time of prescribing or dispensing.

Rather than systems that monitor specific medications or individuals, a complete medication recording system which at the time of prescribing or dispensing makes a full medication record available would greatly enhance the ability of health professionals to detect potentially problematic pharmaceutical use. This would have a number of benefits beyond prevention of pharmaceutical misuse such as to ensure a full record of medications is available for hospital admissions, and would enable health professionals to access a complete medication record when checking for drug interactions. An example of such a system is operating in British Columbia and known as Pharmanet system (Ministry of Health Service, B. C. 2010).

A system that is integrated into current prescribing and dispensing software would have least impact on provision of health services. Whilst there are concerns with diversion of pharmaceuticals, an important consideration for any monitoring system is ensuring that effective treatment is not overly restrictive, and that, where identified, problematic pharmaceutical use attracts a therapeutic rather than a law enforcement response in the first instance.



Initiatives to reduce prescription shopping

A revised prescription shopping program is currently in operation, though this program was modified and relaunched after changes in privacy laws resulted in its suspension in 2002. The current system only includes registered prescribers and does not cover all medications.

There appears to be many limitations with the prescription shoppers information system since its re-introduction. Recent research reports and Parliamentary Inquiries have recommended that this sort of monitoring needs to be undertaken as part of a real time on-line system that covers all prescriptions, such as described above (Drugs and Crime Prevention Committee, 2007; Nielsen et al., 2008b). Such a system would have considerable advantages over systems that only monitor specific substances or individuals.

Treatment

Dependence on prescribed medications can be effectively treated. As with dependence on tobacco, alcohol, and illicit drugs, no single treatment is appropriate for all individuals and treatment plans must take into account the type of drug/s used and the needs of the individual. Appropriate treatment regimes may need to incorporate a number of components and multiple courses of treatment in order to assist recovery (National Institute on Drug Abuse 2005). The modalities that are available for treating dependence on a range of substances are outlined in ADCA's policy position paper on treatment.

Poor access to treatment has been identified as contributing to unsanctioned use of pharmaceutical drugs, and as such reducing barriers to treatment (including costs of treatment and stigma associated with treatment) is essential in reducing pharmaceutical misuse (The Royal Australasian College of Physicians, 2008). In addition, treatment services tailored to meet the needs of prescription opioid users are important in attracting new cohorts of opioid dependent people into treatment.

National policy on medicines

The quality use of medicines is one of the central objectives of Australia's medication policy. The approach and principles necessary to achieve this objective in Australia are set out in the National Strategy for Quality Use of Medicines. The strategy defines quality use of medicines as the use of medicines 'judiciously, appropriately, safely, and efficaciously' and the minimisation of misuse which is defined to include overuse and underuse. (Department of Health and Ageing, 2004).

The document encourages strategy partners to be aware of the quality use of the medicines policy framework and to integrate their activities with the national strategy. Strategy partners include healthcare consumers, health practitioners and educators, healthcare facilities, the medicines industries, the media, healthcare funders and purchasers, as well as governments.

Medicines regulation

There are a number of regulatory measures used in Australia that help to minimise the harms associated with misuse of prescription medicines. Most medicines are listed or registered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied to consumers. This listing or registration process involves an assessment by the Therapeutic Goods Administration (TGA) of the risks associated with the use of the medicine. A product's risk is determined by a number of factors, including whether it contains a substance scheduled in the Standard for the



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Uniform Scheduling of Drugs and Poisons (SUSDP) and whether there may be any adverse effects from prolonged use or inappropriate self-medication. Medicines assessed as having a higher level of risk must be registered rather than listed and are only available on prescription (Therapeutic Goods Administration 2008).

Access to many medicines is further controlled through scheduling. Scheduling in Australia is legally a State/ Territory matter, but jurisdictions adhere almost entirely to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) through inclusion of the SUSDP schedules into their legislation. Many of the drugs referred to in this paper have a Schedule 8 listing which recognises that, while these substances have legitimate therapeutic uses, they also have a marked potential for misuse and require special controls. Such controls may include restrictions on the amount supplied and number of repeats allowed. Other scheduling controls involve the forwarding of scripts to the health department once they have been dispensed as well as recording of sales and maintenance of secure storage.

From 1 May 2010, amendments to the law regulating the sale of pain relievers containing codeine mean that analgesic products containing codeine:

- will not be available as a Pharmacy Medicine (Schedule 2)
- which contain up to 5 days treatment with a maximum dosage unit of 12mg codeine will be available as a Pharmacist Only Medicine (Schedule 3)
- in larger pack sizes (i.e. greater than 5 days treatment) and/or higher strengths of codeine (i.e. greater than 12 mg codeine) will only be available by prescription.

Cold and flu products containing codeine will be unaffected by the scheduling changes meaning that cold and flu products containing up to 6 days treatment will remain as Pharmacy Medicines (Schedule 2). ADCA supports these scheduling amendments which will tighten the availability of products that have been identified as prone to misuse.

ADCA's Policy Recommendations

ADCA makes recommendations in a number of key areas such as education, treatment, health professional interventions, and supply reduction interventions for stimulants:

Education

• ADCA recommends a concerted national focus on raising awareness of the risks associated with the misuse of prescription drugs and over-the-counter medicines

Treatment

- ADCA recommends reducing barriers to Opiate Substitution Therapies (OST)
 - Remove cost barriers but include OST on the Pharmaceutical Benefits Scheme to be consistent with other treatments for chronic conditions
 - Reduce stigma associated with OST by providing greater flexibility in the way treatment can be delivered
- ADCA urges that further research be undertaken into areas where the evidence base is limited such as the appropriate management of poly-drug dependence, which frequently

involves dependence on prescription drugs and effective treatment approaches for prescription opioid dependence

Health Professional Initiatives

- ADCA recommends continued support for initiatives that develop and encourage good prescribing practices among practitioners and that encourage practitioners to adopt strategies to reduce the harms associated with the misuse of prescription drugs such as the Royal Australian College of General Practitioners' guidelines for prescribing benzodiazepines and the Prescription Opioid Policy (The Royal Australasian College of Physicians, 2008).
- ADCA supports the further development, implementation and evaluation of initiatives that identify and address harmful prescription drug use in the community, including projects to reduce prescription shopping
- ADCA endorses better coordination between GPs, addiction medicine specialists, pain medicine specialists and pharmacists
- ADCA recommends that there be increased support and training for health practitioners in identifying those at risk of dependence, addressing and providing appropriate management and referral

Prevention of supply of pharmaceuticals used as precursors for stimulants

- ADCA offers its continued support for the National Strategy to prevent the Diversion of Precursor Chemicals into Illicit Drug Manufacture, the Asian Collaborative Forum on Local Precursor Control, and the South Pacific Precursor Control Forum, to improve cross-border intelligence and detection
- ADCA recommends the continued support for *Project STOP*, to increase information on retail sales of pseudoephedrine precursor chemicals; and
- Support for the Code of Practice for Supply Diversion into Illicit Drug Manufacture, a voluntary agreement between law enforcement, chemicals, science and allied industries.

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