



Comments by the Pharmacy Guild of Australia on the discussion paper to support the development of the National Drug Misuse Strategy (NPDMS)

Introduction

The Pharmacy Guild of Australia (the Guild) is the national peak pharmacy organisation representing community pharmacy. It strives to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

The Guild welcomes the opportunity to respond to the Discussion Paper, *'A Matter of Balance'*, to support the development of the National Pharmaceutical Drug Misuse Strategy (NPDMS) which will be used as the basis to inform and guide the national consultation process.

The Guild notes that the NPDMS will cover both prescription and non-prescription medicines, with particular focus given to pharmaceutical medicines subject to non-medical use, misuse and/or diversion that cause the most harm. The prescription medicines of relevance include opioids, benzodiazepines, psycho-stimulants, anti-depressants, anti-psychotics and performance and image enhancing drugs. The non-prescription medicines of relevance include codeine-containing analgesics, pseudoephedrine and anti-histamines.

However, the medicines that have been identified as associated with the greatest level of harm in Australia and focused on in the discussion paper are opioids, in particular oxycodone, long acting morphine; benzodiazepines, in particular alprazolam; and non-prescription codeine-containing analgesics.

The Guild strongly supports the need to balance the prevention of harm caused by misuse, while continuing to ensure that those who have a medical need can continue to access a clinically appropriate supply of these medicines, and that their use is in no way stigmatised.

Community pharmacy continues to redefine itself given the significant changes occurring to the Australian health landscape, including the formal and standardised structuring of Australia's response to pharmaceutical misuse within a national strategy, which needs to recognise the role of community pharmacy as vital in addressing issues relating to the misuse of pharmaceuticals.

The Guild has been a leader in developing initiatives to support pharmacy in addressing the diversion and misuse of commonly used medicines and would welcome an opportunity for the community pharmacy sector to be involved in the development of the Strategy and implementation of the initiatives to achieve a nationally consistent plan for the reduction of pharmaceutical misuse and the minimisation of harm to the community.

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1. The Scope of the NPDMS

The Guild supports the development of the NPDMS and the emphasis on the Quality Use of Medicines (QUM) as one of the central objectives of the National Medicines Policy.

The Guild believes that QUM is best supported by the supply of medicines through a pharmacy with access to specialised professional support and advice from a pharmacist. Schedule 8 (Controlled Drugs) and Schedule 4 (Prescription Only) medicines require supply from a prescription written by an authorised prescriber, with counselling available from a pharmacist at the time of dispensing. Schedule 3 (Pharmacist Only) medicines are available without prescription at the pharmacist's professional discretion. The pharmacist assesses the need and provides the necessary counselling for safe and appropriate use.

The Guild supports all of the key issues that will be focused on in the NPDMS listed in section 2 of the Discussion Paper, in particular, the investment in healthcare workforce development needs of prescribers and pharmacists, and the examination of what regulatory, monitoring and investigative resources are required to effectively address prescriber/pharmacy shopping and the illicit supply of pharmaceuticals for profit, including consideration of timely and appropriate information exchange between health and police agencies.

The Guild strongly agrees that for pharmaceutical medicines, pharmacists need to be consulted and involved in strategies to reduce abuse or misuse, and as such, acknowledges the recognition of pharmacists as a key stakeholder in the development of the NPDMS.

2. Pharmacists are a key stakeholder

The network of over 5,000 community pharmacies has demonstrated the ability and willingness to implement national drug policy strategies and programs. This is achieved by working in partnership with other health professionals to deliver accessible, integrated, safe and effective care to the community based on QUM principles.

Over a number of years, the Guild has demonstrated support for harm minimisation strategies in the Australian community, including:

- provision of drug-related specific services such as:
 - needle, syringe and other injecting equipment sales
 - safe collection and disposal of syringes
 - opioid dependence treatment programs
- benzodiazepine reduction programs with supervised doses
- Project STOP online 'real-time' recording system for the sale of pseudoephedrine-based products
- smoking cessation advice and treatment
- provision of information regarding drug-related conditions (hepatitis C, HIV/AIDS etc)
- provision of information to family and friends of illicit drug users
- inter-professional liaison and referral to appropriate treatment agencies
- the implementation of public health campaigns.

Following publication of the *Galbally Review of Drugs, Poisons and Controlled Substances Legislation* (Galbally Review) in 2001, the Guild has been active in demonstrating the significant public benefit of retaining the current medicines scheduling arrangements, including the two separate over-the-counter (OTC) schedules (Pharmacy Medicines/Schedule 2 (S2) and Pharmacist Only Medicines/Schedule 3 (S3)). The evidence gathered via the “Mystery Shopper” program, with data collected since 2002, demonstrates the extent of intervention in direct product request sales, as well as the level of compliance by pharmacy staff with the standards and protocols applicable to the supply of Schedule 2 and Schedule 3 medicines. These protocols aim to ensure pharmacists’ involvement in appropriate supply of these medicines, including in those cases where there is the potential for harm and/or misuse/abuse of medicines.

In 2010, the Guild produced *The Roadmap – The Strategic Direction for Community Pharmacy*¹, providing an analysis of where pharmacy is today and a plan for its future direction. Importantly, the ‘Roadmap’ provides practical mechanisms through which community pharmacy can develop future services nationally and includes a number of templates for services of relevance to the NPDMS.

3. Response to Discussion paper Questions

We have responded only to those aspects of the Discussion Paper where we have particular interest.

Question 1 - Are there any other key stakeholders of relevance to the development of the NPDMS?

The Guild suggests the following groups are also important stakeholders in developing and/or progressing strategies, policies and processes relating to the misuse or abuse of medicines:

- Therapeutic Goods Administration (TGA)² – responsible for the regulation of therapeutic goods
- National Health and Medical Research Council (NHMRC)³ – peak body for supporting health and medical research and for developing health and clinical guidelines for the community, health professionals and government
- Health Workforce Australia (HWA)⁴ – involved in health workforce planning, policy and research, clinical education and innovation and reform of the health workforce to respond to community needs
- Professional Registration Boards⁵ – responsible for making registration and notification decisions for registered health professionals based on national policies and standards set by the relevant National Board.
- Health professional training bodies (under-graduate and post-graduate) – involved in preparing and training health professionals to provide effective professional services to meet community needs
- National Medicines Policy (NMP) Committee⁶ - providing advice on medicines policy related issues within a QUM framework
- Council of Australian Therapeutics Advisory Groups (CATAG)⁷ – a collaborative national organisation comprising representatives from all jurisdictional therapeutic advisory groups.

- Lead Clinicians Groups (National and Local)⁸ – providing clinical leadership and advice at both national and local level to inform the delivery of safe and higher quality care, consistent with evidence based clinical practices and service delivery
- Medicare Locals and Local Hospital Networks⁹ – key components of the National Health Reform Agenda providing better health services and a strong local focus for Australia’s health system

Question 2 - Are there any other significant gaps in our knowledge?

Yes. Other significant gaps in the knowledge would be in relation to the percentage of people who are using opioids inappropriately in pain management as opposed to the percentage of people who are using prescribed opioids as a substitution for illicit opioids. This issue needs to be addressed; however there is lack of data on the scale of this problem.

Question 3 - How do factors impacting on the social determinants of health impact on the misuse of pharmaceuticals?

The Guild supports the notion that the misuse of pharmaceuticals should not be seen exclusively as a medical problem but understood in its broader social context. It is essential that legitimate patients are not affected, as many of the medicines associated with pharmaceutical misuse are used by patients with chronic pain or who are under palliative care. The Guild has identified the following social determinants of health as being of significance when considering the impact on the misuse of medicines.

Ageing Population

It is important to ensure support for the Australian population as it ages. Older people tend to suffer from a greater number of health conditions and as such, are generally on more complex medicine regimens to assist in managing their health. Community pharmacists are cognisant of the special needs of older Australians and provide an array of services relating to medicines use, such as medicine reviews, DAAs, and medicine profiles. Community pharmacies undertake these activities for the ageing population in recognition of poly pharmacy for this population, which can result in alarming rates of medicine-related problems, often brought about by confusion through receiving medical advice from more than one medical provider, short term admission to acute care facilities and discharge without adequate follow up and support, or the pervasive encroachment of diseases such as diabetes and dementia or the condition of incontinence.

Health Literacy

Health literacy is a serious issue and we are concerned that not only do people not read the labels, but when they do, they often do not understand what they are reading. A survey¹⁰ conducted by the Australian Bureau of Statistics (ABS) identified 46% of Australians aged 15 to 74 years as not having sufficient literacy skills to meet the complex demands of everyday work and life, and that on the health scale, 60% attained scores below the minimum requirement to meet everyday needs. The ABS survey also identified that only 36% and 38% of people whose language was not English attained scores at or above the level that demonstrated sufficient prose and document literacy respectively to meet everyday needs.

The Guild supports the consideration of a person's expectation of the potential benefits of medicines which is a result of increasingly well informed patients. The Guild draws attention to the National Health and Hospitals Reform Commission Report released in 2009 which identified 'taking responsibility' as a major theme, with one of the most important calls to action being the need to increase and support health literacy for consumers. As community pharmacists are Australia's most accessible health professionals, utilising the community pharmacy network is a cost effective option for delivering initiatives aimed at improving health literacy, especially relating to the use of medicines.

Internet Use

The impact of the internet is an area the Guild recognises is a particular issue that needs to be addressed in order to regulate and enforce access to medicines. The Guild believes that the internet poses both challenges and opportunities for the NPDMS and the pharmacy profession. The growing trend of sale and purchase of analogue medicines, 'legal highs' and pharmaceutical products over the internet within Australia and internationally creates an environment conducive to the uncontrolled and unregulated supply of controlled and/or prescription only medicines, as well as the supply of substandard and/or counterfeit pharmaceutical products.

Pharmacies conduct business over the internet under a range of models: there are e-pharmacies that conduct their business almost exclusively over the internet, and there are community pharmacies that offer 'web portals' as an adjunct to their main business. The Guild recognises that internet pharmacy is an area of rapid growth which improves consumer access and choice. However these advantages should be balanced against potential dangers and protection of patient safety and public health, particularly when consumers purchase products that bypass regulations or safety standards. Many of the medicines that can be obtained via the internet have a potential for abuse or misuse and could cause considerable adverse effects.

The Guild believes that the ideal way to dispense and receive medicines is through face-to-face contact with a pharmacist, as there are benefits for the consumers to have the opportunity for advice from a pharmacist when they have a medicine supplied. The nature of the internet sale/purchase of medicines could make promoting QUM difficult and it is of concern that some medicines are readily available from online suppliers who have no professional qualification or healthcare expertise.

Preventative measures to combat this could include:

- Requiring e-pharmacies to have a process for consumers to have a meaningful consultation with a pharmacist.
- Regulatory requirement to ensure face-to-face interaction between the health professional and consumer, for example, all internet orders for medicines that have potential for abuse/misuse to be accompanied by a prescription with mandates for pharmacist counselling. While it is recognised that this measure will reduce the level of convenience by consumers and can impact Medicare costs, the disadvantages would be outweighed by the public health benefit of this measure.
- Specific provisions and guidelines for online pharmacies and internet sites to adhere to in dealing with re-scheduling of pharmaceutical products. For example, recent codeine re-scheduling changes and controls must also be adhered to by the online pharmacies.
- Extension of a Project STOP – based measure to internet pharmacies requiring them to use purchaser's unique identifier.

- Regular checks and monitoring of internet sites selling medicines.
- Public awareness and education programs to warn consumers about the potential dangers of purchasing over the internet.

Question 4 - How do these agendas and strategies impact on Australia's responses to pharmaceutical drug misuse?

The strategies highlighted in sections 4.3 to 4.7 of the Discussion Paper provide a number of recommendations to address the issue of abuse/misuse of medicines. From a pharmacy perspective, those of most relevance include:

- de-stigmatisation of the issue to facilitate access to appropriate clinical support and services
- maintaining a skilled workforce to deal with the issue and ensuring patients have access to best-practice evidence-based care within a QUM framework
- more complete and accessible patient health records – pharmacists are well placed to support the management of a person's medicine profile to include both prescription and non-prescription medicines
- real-time monitoring enabling clinical decisions regarding patient care – dispensing histories provide the most complete records for supply of prescription items and provides opportunities for pharmacists to be informed about a patient's previous supply history, including identifying the need for clinical intervention
- demand reduction through the availability of adequately subsidised national Opioid Dependence Treatment (ODT) programs
- appropriate medicine management support such as Staged Supply services, Dose Administration Aids (DAAs) and medicine review services – (see question 17)
- multi-disciplinary care, ensuring patients have access to the most appropriate care from the right health professional with effective referral pathways – with real-time monitoring, pharmacists are well placed to identify patients accessing at-risk medicines inappropriately for referral to the medical practitioner or alternative specialised clinical service centres
- improved regional care and coordination – the establishment of Medicare Locals and relevant advisory bodies should result in better coordinated and integrated care at a local level.

The Guild considers that an end outcome of these strategies must be the better management of patients. Prescribing checklists or protocol for continuing opioids treatment for CNMP as part of the doctor prescribing software could also be included as a preventative measure to combat the impact of pharmaceutical drug misuse.

Question 5 - How do the current operations of the PBS contribute to, or reduce, the misuse of pharmaceutical drugs?

The PBS provides reliable and affordable access to life-saving and disease preventing medicines for at-risk patients. One of the major strengths of the PBS is that it is a national program, ensuring a consistent approach to medicine evaluation and registration and to the pricing of PBS items.

However, there are many medicines with the potential for abuse or misuse listed on the PBS. Although systems are in place to regulate the prescribing and dispensing of PBS medicines, these are not always followed.

Further, the Guild contends that the PBS is regarded as a cost management measure and at present has no role as a meaningful clinical intervention tool. Consequently, any inappropriate prescribing takes some time to be identified and much of the harm has already occurred.

Regulation 24

Regulation 24 of the National Health Regulations 1960 permits the supply of multiple repeats for medicines prescribed under the PBS, but pharmacists may be approached to provide multiple repeats when 'Regulation 24' has not been endorsed on the prescription by the prescriber or for non-PBS products. Anecdotal reports also suggest that some online pharmacies in particular, promote the dispensing of multiple repeats as a means of cost-saving or convenience to the patient. Flexibility is needed to allow for legitimate situations when patients may require multiple repeats. It is the responsibility of the pharmacist to assess these requests, taking into account the QUM principles. Cost-savings and convenience are not acceptable reasons to support such requests as it may result in wastage if a patient's regimen subsequently changes, not to mention the inherent risks with potential misuse.

Prescribing/Dispensing Guidelines

Acknowledging the comments on page 26 of the Discussion Paper that poor prescribing and dispensing practices contribute to the misuse and/or abuse of medicines, it should be noted that the PBS does not have requirements for clinicians to follow prescribing or dispensing protocols. These are addressed to some extent by regulations, but primarily by relevant Professional Boards.

The majority of medicines on the PBS have no restriction on their therapeutic use. However, the PBS can provide some level of control by listing medicines for specific therapeutic indications (Restricted Benefits) or requiring relevant authorisation for prescribing certain medicines as a subsidised benefit (Authority Required Benefits)¹¹. While many of the medicines at risk of abuse or misuse such as opioids are listed as Restricted Benefits, it is not known to what extent this is assessed. Pharmacists generally do not have information on a prescription that identifies the therapeutic condition for which the medicine has been prescribed; therefore the onus rests with prescribers to ensure they prescribe according to PBS requirements.

Opioid Dependence Treatments

Under current arrangements, ODT services are not subsidised on the PBS. Nor is the Staged Supply of medicines subject to misuse and/or abuse. Under the PBS, pharmacists are paid to dispense a single quantity issue only.

The Guild acknowledges that funding an ODT or 'Staged Supply' service under the standard PBS and utilising the PBS Safety Net could add significant burden to the cost of the PBS. However, the affordability of ODT services is an issue for many opioid dependent patients and there is a need to explore the financial implications of funding through alternative programs in order to reduce the financial barrier for at-risk patients.

Question 6 - What role do police agencies and other law enforcement agencies have in responding to problems of pharmaceutical drug misuse?

No comment

Question 7 - To what extent are pharmaceutical drug misuse problems impacting on policing agencies in different jurisdictions

No comment

Question 8 - What can we learn from other countries' experiences with problems with, and responses to, pharmaceutical drug misuse?

No comment

Question 9 - What, if any, unintended consequences might be expected in Australia if levels of access to medications such as opioid analgesics were to be reduced? What strategies could be put in place to avoid these unintended consequences?

The Guild appreciates the acknowledgement on page 1 of the Discussion Paper that the medicines being discussed 'are highly beneficial to many individuals and there is a need to ensure that the clinically appropriate supply of these medications is maintained and use is in no way stigmatised'. This is in line with the *National Pain Strategy's* Strategic Action Plan.

We also acknowledge and agree with 'the need to have measures in place to minimise the harm from the unsanctioned use of these medications', whether that be intentional or unintentional. However, we are concerned that the introduction of such measures does not supersede the professional responsibilities of clinicians. Health professionals should be supported to enable them to make a professional clinical decision regarding the prescribing and/or supply of these medicines.

Unintended consequences

We are concerned that should the level of access to these medicines be reduced, there could be the following unintended consequences:

- i. Legitimate patients may be delayed in accessing their medicines, resulting in poorer control of their condition. It is essential that palliative care patients or well-controlled chronic pain sufferers are not hampered in accessing their medicines. Different jurisdictional regulations regarding Schedule 8 medicines already impacts access (see Question 15).
- ii. Pharmacy work flow – further restrictions can have a significant impact on pharmacy workflow, reducing the capability of pharmacists to meet all of their professional obligations. As an example, the re-scheduling of non-prescription codeine containing analgesics (CCA) from Schedule 2 to Schedule 3 had a significant impact on pharmacy workflow. Not only will patients requesting a CCA have to wait until the pharmacist is available to assess each request, there will be a significant impact on the pharmacist's capacity to effectively perform all of their professional obligations, particularly in pharmacies with only one pharmacist on duty. Pharmacists are rightly expected to be professionally responsible for all aspects of medicine supply, but if they are overstretched, there is a risk that some aspects may be neglected, which could impact on the public from a safety and/or quality of care perspective.

- iii. Additional business costs – in order for pharmacist owners/managers to continue to meet their professional obligations, there may be a need to engage additional pharmacists. This can be a significant business cost.
- iv. Pharmacy storage capacity – schedule changes to medicine categories can have a significant impact on pharmacies. As an example, with the schedule changes for CCA in May 2010, many pharmacies had to significantly increase their Schedule 3 storage area to store this large range of medicines. As Schedule 3 medicines must be stored to prevent public access, this sometimes meant encroaching on dispensary space. Pharmacies plan their dispensaries to maximise correct product selection when dispensing, so any impact on storage can have a negative consequence on dispensing practice, requiring pharmacists to implement additional quality control measures.

If medicines are rescheduled from Schedule 4 to Schedule 8, this too can impact pharmacy's storage capacity as pharmacies must store Schedule 8 medicines within safes that meet jurisdictional regulations. Increasing the range of products that must be stored within the drug safe could have a detrimental impact, causing pharmacies to limit the amount of other Schedule 8 medicines they stock which could impact other legitimate patients. It could also mean storing of Schedule 8 products in a way that hinders accurate product selection, increasing the risk of dispensing error for these medicines.

Proposed strategies

We believe that scheduling changes are not the most effective means to address the issue of abuse/misuse of medicines. As the majority of people using medicines are legitimate patients, health professionals and patients need adequate systems and resources to support the professional management of the clinical conditions presented. Detecting people who abuse or intentionally misuse these medicines should be a secondary consideration.

The Guild remains committed to real-time electronic monitoring systems as the best way to address issues of medicine misuse. Systems such as the Electronic Recording and Reporting of Controlled Drugs (ERRCD) and Project STOP (see question 17) allow the collection of data which can be used by governments and health bodies to provide hard evidence for decision making. They provide health professionals with decision-support tools to ensure they can practice in a manner consistent with QUM principles. By targeting particular problem groups in the community, they can also retain appropriate access to medicines for the general public.

In addition, health professionals need clear and concise clinical guidelines and timely referral pathways for patients with clinical conditions that are managed by medicines at risk of being abused or misused. When patients are identified as requiring greater clinical intervention to support the management of the condition and/or to address medicine abuse/misuse issues, there must be systems in place for these patients to be referred to appropriate clinics/clinicians in a timely manner. Care plans should be promoted and encouraged for patients receiving combinations of benzodiazepines and opioids for pain relief.

Question 10 - To what extent is there a current evidence/practice gap in Australia concerning the use of opioids for CNMP?

Product efficacy

A large number of non-prescription analgesics are available in Australia, many of which have been available for many years for indications that were accepted with much lower levels of evidence than now required. These products have not previously been required to demonstrate their efficacy for registration on the Australian Register of Therapeutic Goods (ARTG) due to their grandfathering onto the register. The Guild is aware of claims that CCA do not contain sufficient codeine to be effective as an analgesic. The lowest dose of codeine producing significant analgesia is not well defined.

In acute pain of moderate intensity, studies suggest that on average a dose of 30 mg of codeine is required to produce an analgesic effect. For persistent pain, the lowest effective dose should always be used. The recommended dose for codeine is 30 to 60 mg every 4 to 6 hours.¹² The amount of codeine in CCA ranges from 8 to 15mg:

- Panadeine® - contains 8mg codeine phosphate (which is not in the class for risk and not subject to misuse)
- Nurofen Plus® - contains 12.8mg codeine phosphate
- Panadeine® Extra – contains 15mg codeine phosphate

The Guild agrees that product efficacy is imperative to justify supply within Australia and has been of the view that efficacy is a registration/licensing issue under the domain of the TGA.

Professional Practice

We acknowledge there can be significant variation in professional practice for both prescribers and pharmacists. Poor professional practice tends to be managed more as disciplinary proceedings by relevant Professional Boards¹³. We would support implementing support systems for clinicians whose prescribing or dispensing of medicines subject to abuse/misuse indicates an opportunity for practice improvement where action is more rehabilitatory than disciplinary. Understandably, repeat offenders that do not rehabilitate should be appropriately disciplined, but poor practices may be more a result of poor internal systems or processes rather than intentional professional irresponsibility.

Such measures would require the support of the relevant Professional Boards and could implement targeted quality improvement as part of professional development for identified clinicians. Adequate resourcing or professional organisations and training bodies to develop appropriate rehabilitation courses would be essential to implement this corrective measure.

Specialised clinical support

Delays or lack of access to specialised services to support pain management significantly contributes to the use of opioids for CNMP. There are significant waiting times to access pain clinics or services that look at pain control in the broader spectrum, with consideration also of non-drug therapy.

Many health professionals may not be aware of what services are available for referral, particularly in rural and remote areas. Community pharmacy could be better utilised to support patients in these areas, acting as intermediaries or facilitating access to distant health professionals through telehealth services. We note that under the National Health Reform Agenda, the Australian Government is funding an initiative¹⁴ to provide Medicare rebates for online consultations across a range of medical specialists. Community pharmacy could play a vital link for patients in rural and remote locations with chronic pain, mental health or medicine abuse problems. Consideration should be given to funding pharmacies under this initiative.

Clinical Guidelines

Health professionals need access to clear, concise clinical guidelines that have been developed in consultation with a broad range of relevant stakeholders. Resources also need to be streamlined so that health professionals are not confused by where they should go to access support.

Agencies such as the NHMRC could be engaged to develop overarching guidelines that are cross-sectorial and multi-disciplinary and organisations such as the National Prescribing Service (NPS) could be engaged to develop assessment and counselling tools to complement these guidelines in supporting the full range of health professionals. Professional organisations and training bodies could then be engaged to streamline these guidelines to prepare and train specific professional groups. We note that there are guidelines and resources available for pain management, but there tends to be more for managing acute pain, e.g. NPS Managing Pain¹⁵.

National Pain Strategy

We note the National Pain Strategy identifies a number of key strategic actions to meet their goals in improving the quality of life for people with pain, including:

- 5.1 – improving the education and information materials for consumers, carers and other supporters, health workforce etc, to improve understanding of a range of issues including best-practice management for chronic pain, management of pain medicines and where to go for appropriate health care services
- 9.1 – validating and implementing a brief universal standardised screening/assessment tool for pain
- 9.7 – providing a toolkit for primary care practitioners, including a template pain management plan
- 9.8 – providing a directory to inform health practitioners of existing resources
- 9.9 – promote training in inter-disciplinary/inter-professional practice and joint meetings of professional organisations
- 13.2 – establish communication channels (e.g. teleconference team meetings if at different sites)
- 17.1 – develop and promote use of guidelines for quality use of pain medicines in the community

Question 11 - To what extent is there a current evidence/practice gap in Australia concerning the use of benzodiazepines for conditions such as anxiety and insomnia?

There are limited guidelines available for the use of benzodiazepines and other hypnotics, and we suggest that many health professionals may be unaware of what is available. We note the TGA has information and recommendations on the use of Zolpidem¹⁶ and the NPS has a position statement on the use of Zolpidem¹⁷, but we question how effective these are in changing behaviour.

Recommendations for changes in behaviour require more than mere notification. Ongoing commitment is required to develop change management strategies with training, promotion and professional support. It should also be noted that recommendations do not mandate practice behaviour.

We note the TGA's information 'encourages doctors not to prescribe and pharmacists not to dispense more than a single pack at one time'. Unless there is a clear delineation of responsibility, it is unlikely that a pharmacist would challenge a prescriber's professional discretion to prescribe more than one pack at a time. Additionally, intended consumption should not exceed the dosage indicated by the doctor over a period of time in line with clinical guidelines.

As discussed under Question 10, the Guild would like to see:

- rehabilitation support mechanisms in place for prescribers and pharmacists who demonstrate room for improvement with their prescribing/dispensing practices
- greater awareness of referral pathways to specialist sleep clinics or other support agencies
- improved and timely access to specialist sleep clinics to reinforce the referral pathway
- clear and concise clinical guidelines with multi-disciplinary application.

Question 12 - Is there other evidence of harms stemming from pharmaceutical misuse?

In addition to those proposed within section 9 of the Discussion Paper, the following harms can also stem from pharmaceutical misuse:

- Driving, operating machinery or handling weapons while under the influence of medicines that cause sedation or affect alertness or concentration can have serious consequences. While many medicines must be labelled with appropriate warnings regarding driving and sedation, it is questionable how often this is followed by patients.
- Alcohol and medicine use – alcohol can interact with many of the medicines at risk of being abused/misused. The consequences can be increased sedation affecting alertness/coordination. It may also affect blood-alcohol levels resulting in patients being over the limit on less alcohol.
- All the at-risk medicines can affect alertness and coordination, with the elderly being at particular risk. Such effects can result in difficulty with self-care and/or increased risk of falls.
- Dental decay from cough mixtures – the Guild is aware that the abuse of cough mixtures containing codeine or derivatives can result in severe dental problems because of the high sugar content.

- Cough mixtures containing dextromethorphan – the Guild is aware of reports from the ACT about instances of ‘teenagers’ seeking out dextromethorphan based products without providing valid reasons for use. ACT Health issued advisories to ACT pharmacists in August and December 2009. There are also websites and internet forums which encourage the recreational use of dextromethorphan based products, describing dissociative or ‘out-of-body’ experiences.¹⁸
- A consequence of unintentional misuse also exists for elite sports people. We are aware of elite sports people inadvertently taking prescribed and non-prescription medicines which may be banned for particular sports categories, resulting in disqualification or bans for the sports person.
- There is a concern that harm can also extend to the patient’s family and children in particular and there is a need for socio-psychological measures to support the family which can become dysfunctional as a result of pharmaceutical misuse by an individual.

Question 13 - Certain groups in the community (such as those living in rural areas and those experiencing social disadvantage) appear to be disproportionately affected by levels of harm associated with pharmaceutical drug-related problems. What could be done to address this in a targeted way?

In line with previous points raised, the following actions could be implemented to better support disadvantaged groups:

- Improved access for rural and remote locations, subsidising relevant health professionals to coordinate and/or facilitate distant consultations via telehealth.
- Improving collaborative care with more multi-disciplinary training at undergraduate and post-graduate levels.
- Subsidising medicine management systems such as DAAs or Staged Supply for at-risk patient groups.

Question 14 - To what extent is Medicare Australia’s Prescription Shopping Program able to impact on the misuse of pharmaceuticals?

We believe the Prescription Shopping Program has limited application. It does not capture the supply of non-PBS medicines, non-prescription medicines, nor medicines below the copayment level – though the latter will change from 1 April 2012 when this dispensing data will be transmitted to Medicare Australia.

Real-time monitoring providing health professionals with information to support their clinical decisions will be much more effective. Ideally, both prescribers and pharmacists should have access to a person’s complete medicine history.

The Prescription Shopping Program could potentially be utilised to target prescribers and/or pharmacists with less than ideal prescribing/dispensing practices in order to implement a quality improvement rehabilitation training schedule.

Question 15 - How effective is Australia’s current approach to the regulation and monitoring of these medications and how could the current approach be improved?

The Discussion Paper has identified the differences in regulations between the jurisdictions as problematic. This has been enhanced with the national registration of health professionals and is particularly noticeable in border regions where practitioners may regularly practice in more than one jurisdiction.

Ideally, we would like to see national regulations recognised by all jurisdictions, providing all health professionals with common regulatory requirements. We note that there are national regulatory instruments such as the *Standards for the Uniform Scheduling of Medicines and Poisons* (SUSMP)¹⁹, which have gone a long way to standardising legislation, but much further could be done.

Palliative Care

One area of concern to the Guild is the continuity of care for palliative care patients and their carers. We are aware of situations, generally in border areas, where patients have not been able to access their palliative care medicines because of variations in jurisdictional regulations. This is particularly concerning given these people and their carers are already under considerable stress and anxiety.

Non-Prescription Medicines

The solution to abuse/misuse problems for non-prescription medicines has been to restrict access by making these medicines either Schedule 3 or Schedule 4. The Guild maintains that such scheduling changes will do little to address the issue of abuse of these medicines, whilst restricting access to those people using the products responsibly. Unless pharmacists have access to real-time information regarding the supply, the people who abuse or misuse these medicines learn how to manipulate pharmacists by pharmacy shopping and providing expected responses to pharmacist triage. The solution is for these medicines to be in a notifiable category, with systems integrated with the pharmacy's dispense system, allowing pharmacists to record supply for a particular patient while at the same time having real-time access to records of prior supply.

Question 16 - What are the key issues that arise concerning the balance between measures which are intended to enhance the quality use of medicines (such as a CMMS) and the needs to protect the privacy of patient information?

The Guild supports Australia's National Privacy Principles and notes that as part of their professional responsibility, pharmacists already respect patient's right to privacy regarding their health and medicine history. However, there is a lot of confusion and misinformation about patient privacy.

We suggest that with medicines subject to abuse or misuse, it is not unreasonable for the mandatory sharing of information between health professionals to assist them in making an informed professional decision regarding prescribing or dispensing. With this in mind, consumers should provide informed consent for the sharing of such information, understanding that lack of consent also negates the ability to supply. This situation is in current practice with Project STOP, utilised as a support tool to manage the supply of products containing pseudoephedrine. In some jurisdictions, legislation is in place where consumers must provide identification for recording purposes to enable the supply of pseudoephedrine products. The consumers are informed of the requirement and how lack of identification means the product cannot be supplied.

This is one area of concern we have for the Patient Controlled Electronic Health Record (PCEHR) initiative. Where the sharing of records for medicines subject to abuse or misuse is under direct patient control, it would be expected that legitimate users would be likely to consent to the sharing of information, whereas abusers/misusers would be unlikely to do so.

QCPP

With this in mind, it would also be reasonable to expect health professionals to meet professional quality assurance standards. The Quality Care Pharmacy Program (QCPP) is the only national endorsed quality assurance program in community pharmacy and is now recognised as the National Standard (AS 85000:2011). QCPP procedures outline how a pharmacy should operate and provides the pharmacy team a clear picture of the requirements to facilitate better customer service. QCPP Standard 1.5 requires pharmacies in the context of complying with legislative requirements to ‘maintain and follow a system to ensure patient confidentiality’.

Question 17 - Are there any measures that could be introduced in the short term that would enhance our ability to monitor the prescription and dispensing of these medications?

ERRCD

The *Electronic Recording and Reporting of Controlled Drugs (ERRCD)*²⁰ initiative is being funded under the Fifth Community Pharmacy Agreement. ERRCD will involve implementing a system to collect and report data relating to Schedule 8 medicines to help address problems of forgery, abuse and doctor shopping. Initially, the system will be designed for state and territory monitoring purposes only, with the capacity for utilising the data collected for intervention purposes in the future. In latter stages of the initiative, access to the database could potentially be widened to include prescribers and pharmacists. Refer to the Guild’s ‘Roadmap’ for a template on ‘*Controlled Drugs Real-time Monitoring*’.

Project STOP

For the supply of non-prescription medicines that are subject to abuse, the Guild has developed a monitoring system known as *Project STOP*²¹ which is a working system that could be implemented quickly. The overall objective of Project STOP, based on public health and safety concerns, is to provide a fast and efficient mechanism to community pharmacists to record and monitor sales, in order to check requests for pseudoephedrine based products and supply these products appropriately in accordance with therapeutics standards to support QUM to intervene to prevent diversion of precursor chemicals into illicit drug manufacture. We note that most jurisdictions already have the legislative framework for such a proposal to be implemented relatively quickly. The data from a project STOP system can be accessed by State and Territory Health Departments and law enforcement agencies.

Staged Supply

Staged Supply refers to arrangements where the pharmacist, usually in response to a request from the prescriber, supplies a medicine to the patient over a period of time in instalments rather than supplying the full amount prescribed at the outset. This service has developed over time as a professional courtesy in response to prescriber requests for particular patient groups such as those with abuse/misuse or adherence issues who would benefit from daily supervision of their medicines regimen.

A review was established under the Fourth Community Pharmacy Agreement to examine the implications for community pharmacy of the provision of Staged Supply services. The review examined the circumstances in which Staged Supply might be clinically indicated and the legislative, financial, administrative and practice implications. The review found that demand for Staged Supply is growing and would benefit from defined standards to ensure best practice and record keeping²². Although many of the medicines dispensed may be listed on the PBS, the Staged Supply service is not subsidised under the PBS and costs are either fully or partially met by the patient or absorbed by the pharmacy. The supply of opioids by instalments to specific patients is formalised as an ODT program.

Providing a Staged Supply service may have a number of benefits to the government and community depending on the patient groups supported. Supporting patients with drug abuse/misuse issues can impact the diversion of at-risk medicines. Similarly, supporting patients with adherence issues (e.g. those with mental health problems) facilitates self-management with better health outcomes. At-risk patients can be managed in the community setting rather than through government hospitals or clinics, improving the efficiency of the health system in a cost-effective manner. Refer to the Guild's 'Roadmap' for a template on 'Staged Supply'.

ODT services

ODT services involve the supply in instalments of methadone or buprenorphine to at-risk patients. Current operations vary between jurisdictions and there are limits with the number of participating pharmacies and supported patients. The establishment of a nationally subsidised ODT service would provide a more affordable and accessible treatment program, and would create a financial safety net for those entering treatment.

Medicine Reviews

Under the Fifth Community Pharmacy Agreement, the Australian Government is funding medicine review services such as Home Medicines Reviews (HMRs) and MedsChecks.²³ These could be extended for more targeted pharmacist interventions for people at risk of unintentional or intentional medicine misuse or abuse.

Question 18 - How are the current prescriber remuneration patterns impacting on patterns of pharmaceutical drug misuse?

Supporting patients with chronic pain problems or with substance abuse/misuse issues is complex, and we believe all health professionals should be appropriately compensated for their effort.

The Guild acknowledges that under current Australian legislation, medical practitioners are only permitted to dispense and supply medicines as pharmaceutical benefits in areas where they practise if there is no pharmacy available within a reasonable geographical distance, and approval will be cancelled should a pharmacy open within the area.¹

There is evidence internationally that 'dispensing doctors' tended to prescribe more pharmaceutical items, incurred higher pharmaceutical costs, and were less likely to prescribe generically than their non-dispensing counterparts. In Australia, it has been found that 'dispensing doctors' prescribed significantly fewer PBS prescriptions per patient and prescribed proportionally more penicillin type antibiotics, adrenergic inhalants and non-steroidal anti-inflammatories.²⁴

The Australian Medical Association (AMA) urges caution regarding this matter²⁵, noting medical practitioners who also have a financial interest in dispensing and selling pharmaceuticals or who offer their patients health-care related or other products have a conflict of interest. Further, the AMA states medical practitioners should not dispense pharmaceuticals or other therapeutic products unless there is no reasonable alternative, and where dispensing does occur, it should be undertaken with care and consideration of the patient's circumstances.

Question 19 - To what extent is OST accessibility and dispensing fees impacting on patterns of pharmaceutical drug misuse?

There is a significant potential to increase the number of community pharmacies providing treatment to increase equitable access to such a treatment option, as 80% of consumers receiving treatment in public places have indicated they would prefer to receive their treatment in community pharmacies.²⁶ We believe that supporting these patients to receive their treatment at the community pharmacy setting reduces their risk of exposure to individuals who may promote a return to illicit drug use.

One of the key benefits of ODT programs is their capacity to assist individuals to return to being productive members of society. Giving consumers more flexibility in accessing treatment at various settings throughout Australia and not limiting them to a particular pharmacy or location would require safeguards, such as real-time recording of dispensing data, to prevent misuse or multiple attendances by consumers at varying locations.

Support of such a system would enable appropriate management, transfer, support and monitoring of consumers participating in ODT programs and would minimise the occurrence of misuse or multiple dosing.

The Guild also recognises that affordability of ODT services is an issue for many opioid dependent patients and there is a need to explore the financial implications of funding through alternative programs in order to reduce the financial barrier for at-risk patients.

We believe that the establishment of a nationally subsidised scheme for methadone and other opioid dependence treatments would provide a more affordable and accessible treatment program, and would create a financial safety net for those entering treatment. These initiatives would also lead to a greater number of pharmacies being involved in the program, and a large number of drug users benefiting from it. Refer to the Guild's 'Roadmap' for a template on '*Opioid Dependence Treatment*'.

Question 20 - To what extent are the current patterns of availability of adjuvant drugs impacting on patterns of pharmaceutical drug misuse?

No comment

Question 21 - To what extent are these difficulties impacting on patterns of pharmaceutical drug misuse?

Difficulties in accessing specialised clinical treatment centres can have a significant influence on medicine abuse/misuse. Health professionals should have clear, concise and uniform resources to support them in providing professional clinical support, with a clear referral pathway for complex cases. Delays in referrals may result in at-risk patients being managed within more limited scopes of practice which can have less than ideal consequences such as medicine misuse or abuse.

It should be noted that this issue not only relates to accessing specialised pain clinics, but specialised sleep and mental health clinics as well. In addition, health professionals need to have readily available reference to know what specialised health service centres are available in their area, or alternatively, how to access distant services when not locally available.

Question 22 - To what extent are problems with hospital to community transitions impacting on patterns of pharmaceutical drug misuse?

The transition between hospital and community care is known to be problematic, particularly for people with highly dependent health needs or complex conditions. It is essential that there is effective communication between the hospital and community sectors on discharge. For patients who are being supported in the community by medicine management services provided by their local community pharmacist such as DAAs or Staged Supply, it is essential that their pharmacist is informed of discharge arrangements and changes to their medicine regimen so support services can be maintained.

Community pharmacy is also well positioned to provide or coordinate other support services for identified at-risk patients such as a MedsCheck appraisal or HMR to review the patient's medicine regimen and ensure they understand what medicines they are using, why they are using them and how to use them properly.

Additionally, any person who has been started on opioid pain relief while in hospital should be re-assessed when returning to their general practitioner for continued pain relief should be re-assessed and care plan developed for future management.

Question 23 - To what extent would a CMMS enhance the QUM in Australia?

The Discussion paper suggests that a Coordinated Medication Management System (CMMS) would substantially reduce the risk of inappropriate prescribing but notes that it would not address all of the difficulties associated with the misuse of medicines. The Guild agrees that it is not a stand-alone solution, but any measure that improves prescribing practices has a direct impact on dispensing practices. Pharmacists are directly influenced by prescribing patterns. Medicine issues are sometimes not resolved in a timely manner because at the time the prescription is presented to the pharmacy, the communication channel to the prescriber is not operational (e.g. after hours, prescriber off-duty).

The Guild believes that real-time reporting of supply of at-risk medicines will provide the greatest contribution to managing the abuse/misuse problem, however, used in combination with a CMMS, it could also promote better clinical care for all patients.

Question 24 - How could Australia's data collection and sharing processes in this area be enhanced?

Although there is substantial data currently collected, there are significant limitations to it being used effectively and consistently. First and foremost, relevant data should be available to the frontline health professionals providing clinical care to assist them in making the most appropriate clinical decisions for their patients.

This requires real-time access to data, particularly the supply history of relevant medicines. Electronic prescribing and ERRCD will facilitate improved data collection for both the prescribing and supply of relevant medicines while concurrently supporting quality professional health care.

We have identified the following issues with current data collection arrangements:

- PBS data collected by Medicare Australia is incomplete, collecting neither non-PBS nor below-copayment information.
- Prescribing history does not necessarily reflect dispensing history as people may not fill all of their prescriptions. Dispensing history provides the more complete information for what is supplied and collates information from all prescribing sources.
- The time lag from when Schedule 8 medicines are supplied and when health authorities are notified means any action taken is retrospective.

For collected data to be useful, there needs to be clear definition of the roles and functions of the various service providers and organisations involved in managing and/or responding to the information being provided. There must also be adequate funding and resourcing of relevant service providers and organisations for them to be effective in fulfilling their responsibilities. While ERRCD has the potential to provide an excellent clinical support tool for pharmacists (and eventually prescribers), the involvement of regulatory or law enforcement agencies will need to be clearly enunciated and supported.

Question 25 - Are there any other gaps in the research?

No comment

Question 26 - What other clinical responses are required?

The clinical responses provided in section 13.2 of the Discussion Paper provide a comprehensive approach to managing patients that are coming into the health system. An additional clinical approach that has value is case-conferencing between the supporting health professionals. It should be noted that case conferencing is subsidised under the Medicare Benefits System (MBS) for diabetes and chronic disease management.²⁷ There would be benefit in establishing a multi-disciplinary case conference item number for managing medicine abuse/misuse. In the community setting, pharmacists are often overlooked as important participants in multi-disciplinary case conferencing; however it is essential to include pharmacists to provide expert advice on medicine related issues in the context of QUM.

There also needs to be consideration for clinically managing patients that are already in the health system who have not responded to their management or who have not been managed satisfactorily and have problems with medicine abuse/misuse. For these problem patients, appropriate clinical responses will be to improve access to support programs, involving:

- increasing the number of access points, particularly through community pharmacy
- developing and supporting appropriate training for relevant health professionals
- improving communication channels between supporting health professionals
- appropriate funding of services to ensure cost is not a barrier to at-risk patients and support health professionals are adequately compensated.

Question 27 - What other workforce development responses are required?

The 'workforce development issues' identified in section 13.4 of the Discussion Paper provides a thorough overview of key issues. In looking at workforce issues, the Guild suggests it is also important to consider workflow issues within the clinical settings and ensure measures are in place to support any workflow changes necessary to implement any process changes.

While it is reasonable and beneficial to have clear clinical guidelines promoting good prescribing or dispensing practices, general practices and pharmacies must have effective and efficient workflow arrangements in place to accommodate practice change. Proposed professional education and training should incorporate practice change management as well as clinical training. It should be noted that this may not only involve the training of health professionals but also support staff such as pharmacy assistants and administrative staff.

Shared care plans between GPs and drug and alcohol services should form part of the patient treatment. Consideration should also be given to support drug and alcohol specialists services within the public sector clinics as the availability of the workforce vary across jurisdictions.

Question 28 - What other consumer-oriented responses are required?

The Guild agrees with the consumer-oriented responses in section 13.5 of the Discussion Paper and believes that community pharmacy is well placed to assist with many of these measures. For more information, refer to the Guild's 'Roadmap' for templates on 'Health Literacy', 'Public Health Promotion' and 'Social Support Networks' for information on how community pharmacy can effectively contribute.

The Guild would also like to highlight an issue for which raising consumer awareness would have some benefit. Although jurisdictional regulations require pharmacists to be involved in the supply of Schedule 3 medicines and to confirm therapeutic need and appropriate use, many consumers have an expectation that because a medicine does not require a prescription, they have a right of access.

While the Guild acknowledges the opportunities for continual improvement in how pharmacists manage the supply of Schedule 3 medicines, we have had anecdotal reports from pharmacists how consumers often resent providing them with the necessary information for the pharmacist to make an informed clinical decision regarding supply. Similar to consumer campaigns regarding the over-use of antibiotics, we would like to see consumer awareness programs that informed the public about the requirements for supplying Schedule 3 medicines. Ideally, this would be synchronised with campaigns to support pharmacists and pharmacy assistants in how to better manage consumer requests for non-prescription medicines. We would welcome working with Government and relevant organisations to progress these ideas.

Question 29 - Are there any other potential contributions that technology could make?

Reiterating previous comments, the Guild believes that a real-time monitoring system for both prescription and non-prescription medicines will be integral to successfully curtailing the abuse/misuse of medicines within a suitable clinical framework based on QUM principles. We again make reference to:

- Project STOP – a real-time monitoring system for pseudoephedrine-based products which can be readily adapted to monitor and inform clinical decisions regarding the supply of other relevant non-prescription medicines.
- ERRCD – the initiative funded under the Fifth Agreement, aiming at providing a real-time monitoring and decision support resource for Schedule 8 medicines.

The Guild would like to emphasise that to maximise the effectiveness of these systems, it is important that they are integrated with the pharmacy dispense system to streamline workflow processes.

While Project STOP has been very successful in curtailing the supply of pseudoephedrine-based products to ‘pseudo-runners’, lack of funding has meant that it has not been integrated with pharmacy’s dispense systems. This has meant that in providing its support for this initiative, community pharmacy has managed the additional burden of separate data entry systems.

Question 30 - To what extent is Australia’s current self-regulatory approach to the marketing of pharmaceuticals effective?

The Guild is supportive of the essential regulations for advertising as they are in the public interest and support Australia’s National Medicines Policy and QUM Strategy. However, the regulatory system for advertising is confusing and the majority of pharmacists and the public are often not aware of how advertising approval processes or the advertising complaints system works.

The Co-regulatory model

The Guild is strongly supportive of the existing co-regulatory model of therapeutic goods promotion. The existing system fosters a strong open collaborative partnership between Government and industry organisations. This relationship is vital to ensuring advertisers receive clear guidance and communication in producing responsible advertising which complies with regulatory requirements. The broad coverage of the Therapeutic Goods Advertising Code (TGAC)²⁸ and diverse nature of the therapeutic goods industry would make a self-regulatory model nearly impossible to implement successfully. However, co-regulation requires very clear direction to delineate responsibility and identify the arrangements and processes in place to minimise oversight or lapses.

Advertising guidelines could be improved to ensure greater clarity for reference by all parties involved in the advertising process. As an example, clarity should be given to distinguish advertising claims versus therapeutic claims. For clarification, an advertisement may claim ‘4 out of 5 people prefer Brand A’ and have the data to support this statistic. This is an advertisement claim and should not be confused with therapeutic claims, such as ‘4 out of 5 people respond well to Brand A without any side-effects’.

Price Lists

A recurring issue for pharmacists has been the inappropriate use of price lists to promote therapeutic goods even with the availability of the Price Information Code of Practice²⁹. Concern has also been expressed that the price lists do not advise that for particular medicines also covered by the PBS, dispensing at the ‘listed price’ might negate any of the ‘Safety Net’³⁰ advantages associated with the PBS.

In addition, the Guild is concerned with the inclusion of medicines at risk of being abused or misused such as Schedule 8 medicines and benzodiazepines, often promoted at prices or quantities that could encourage inappropriate use.

The issue of ‘price lists’ is also one for which we are often advised by pharmacists that there appears to be no clear or consistent manner in which complaints are dealt with. We believe the agencies that deal with advertising complaints should be given the jurisdiction to deal with such complaints with strong penalties for repeat offences.

Pharmacy Self-Regulation

The Guild has a current policy on the ‘advertising of medicines’, which supports the view that consumers have the right to make an informed choice about medicines and their health and that publicly available information about medicines must be current, accurate, based on sound evidence and should not promote excessive or inappropriate use.

The Guild considers it best practice to document the clinical decision for any supply of medicines which have a potential for harm/ misuse or abuse.

Pharmacy is a unique retail environment consisting of a retail component combined with the professional service obligations of pharmacy practice. Unlike general retailers, pharmacists have ethical as well as legal responsibilities with regards to advertising activities, which are administered by the relevant registration authority. Advertising guidelines³¹ are available for all registered health practitioners and a breach of the guidelines may constitute unprofessional conduct and/or professional misconduct. Such misconduct may be dealt with by the relevant Board through the disciplinary mechanisms available under the *Health Practitioner Regulation National Law 2009*.

Within community pharmacy, professional self-regulation is also managed through QCPP which has a standard³² for advertising and promotion that is subject to continual review. In summary, this standard requires pharmacy advertising or promotion to:

- comply with the *Therapeutic Goods Advertising Code 2007*
- ensure claims are supported by evidence
- be accurate and balanced
- not promote inappropriate or excessive use and
- ensure price lists comply with the Price Information Code.

Over 80% of community pharmacies are accredited under QCPP and are subject to audit every two years.

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