The Pharmacy Guild of Australia

THERAPEUTIC GOODS ADMINISTRATION

Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response

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INTRODUCTION

The Pharmacy Guild of Australia (the Guild) welcomes the opportunity to comment on the Therapeutic Goods Administrations' (TGA) Consultation Paper on the opioid use and misuse in Australia and the options for a regulatory response.

The Guild is the national peak pharmacy organisation representing community pharmacy. The Guild aims 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 is supportive of addressing the problem of opioid use and misuse in Australia we agree that it is a very important issue that needs an urgent policy response from all levels of Government as well as all stakeholders.

The Guild notes a recent report by the Australian Institute of Health and Welfare[1] which showed a 24 per cent spike in prescriptions for opioids between 2010-11 and 2014-15. This rise was due in part to a 60 per cent increase in prescriptions for oxycodone. In addition the Guild notes Australia's Annual Overdose Report 2017[2] published by the Penington Institute shows that fentanyl, a Schedule 8 (Controlled Drug) which is 100 times more potent than morphine is killing hundreds of Australians amid the country's escalating overdose problem. The Penington Report shows that more than twice as many Australians are now dying due to accidental overdose as compared to those dying from car accidents. A significant increase in deaths related to pharmaceutical opioids, street heroin, and highly potent fentanyl is highlighted in the report. In capital cities and regional areas, Australians are now far more likely to overdose on opioids including codeine and oxycodone than by sleeping tablets such as diazepam followed by alcohol, and then amphetamines.

Real Time Prescription Monitoring

We believe the findings of these and other reports are a wake-up call that governments and health professionals need to work together to implement a nationally consistent real-time monitoring system as a matter of urgency. The nationally coordinated real time recording system must be mandatory and operate across all pharmacies and all doctors' surgeries to be effective.

Whilst the Guild agrees that there is an urgent need to address the opioid problem in Australia and we note the TGA's efforts in this regard, we believe that the TGA's suggestions in the discussion paper are limited because it can only make recommendations within its powers contained in the Therapeutic Goods Act. We do not believe that the suggestions in the TGA's paper will effectively address the problems of the opioid crisis as they do not include a nationally consistent real time monitoring system which is the responsibility of the respective state and territory health departments.

The Guild negotiated for the allocation of $5 million in the Fifth Community Pharmacy Agreement for an Electronic Recording and Reporting of Controlled Drugs (ERRCD). The funds were to support the development of a system to collect and report data relating to controlled drugs, to address the problems of forgery, abuse and doctor shopping. On the 12th of February 2012, the then Minister for Health announced that a licensing agreement had been signed with the Tasmanian Department of Health and Humans Services to use their existing Controlled Drugs monitoring system (DORA) as the platform for the

[1] https://www.aihw.gov.au/reports/illicit-use-of-drugs/non-medical-use-pharmaceuticals/contents/table-of-contents
[2] http://www.penington.org.au/australias-continuing-overdose-tragedy/

nationalised ERRCD system to be made available to all states and territories.[3] Unfortunately to date none of the States or Territories have taken up this offer. However, we note that Victoria announced that it would be developing their own system called "SafeScript"[4]. We believe that this system will address any shortcomings of the Tasmanian system.

SafeScript

Victoria is much further progressed with implementation than any other mainland state and has thoroughly investigated what is required to implement a high performing system on a Victorian and national scale. A feasibility study commission by the Victorian Government revealed a better alternative to address the limitations of the Commonwealth software which in its current state will not meet the needs of clinicians, nor will its interface with clinical systems encourage high uptake. As a result, Victoria has made the decision to develop SafeScript, based on contemporary technology. It will source data from Prescription Exchange Services (PES) - technology that is already used in the majority of pharmacies and medical clinics to facilitate electronic transfer of prescriptions. This approach will have significant advantages. SafeScript will be high performing from the outset, and as it will be developed using modern cloud-based architecture, it will be scalable to an increasing volume of prescriptions. By comparison, significant redevelopment work would have been necessary before the Tasmanian software could have supported Victoria's prescription volume, let alone at a national level.

Most importantly, SafeScript will be designed around clinicians' needs and will offer a better user experience and cause minimal disruption to clinical workflow. Clinicians will receive pop-up notifications from their desktops within seconds after a prescription has been issued or dispensed which will prompt clinicians if a review of the records in SafeScript is necessary. The notification will also provide a direct link to the patient's record. The Commonwealth software does not provide these workflow features for clinicians.

Price Information Code of Practice

The Guild suggests that the TGA should consider reviewing the Price Information Code of Practice (PICP)[5] as the Guild has become aware of price lists which while appearing to meet the requirements of the PICP promote the availability of high quantities of opioid containing medicines at substantially cheaper per unit prices than smaller packs. This raises concerns about inconsistent public messaging regarding increased restrictions of opioid products arising from recent scheduling changes for codeine combination products and substantial consumer education campaigns advising against regular or long term use of this class of products.

Opioid Roundtable

The Guild notes that it has now been almost three years since the Department of Health held an Opioids Roundtable meeting in Canberra on Wednesday 27 May 2015 to assist the Pharmaceutical Benefits Advisory Committee (PBAC) to form recommendations to the Minister on the PBS listings for opioids[6]. The purpose of the Opioids Roundtable was to obtain stakeholder views on the PBS listings and restrictions for opioids. Whilst the focus was on PBS listings, discussion was held in a broader context and covered a range of issues associated with opioid use. Roundtable participants included representatives from consumer groups, industry, government and health professionals. The Guild believes that there is an urgent need for this Opioids Roundtable to be re-convened as part of the TGA's current project so that the issues raised at this meeting and the discussion paper can be re-examined with a view to finding solutions. As part of the agenda for this roundtable, we believe a recommendation

[3] https://www.health.gov.au/internet/main/publishing.nsf/Content/7A1C6A6DE5D4EA5ECA257BF0001959F3/$File/Electronic%20Recording%20and%20Reporting%20of%20Controlled%20Drugs%20-%20locked.doc

[4] https://www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript

[5] https://www.tga.gov.au/price-information-code-practice

[6] http://www.pbs.gov.au/info/reviews/authority-required-listings

should be made to implement the National Pain Strategy, which provides a national framework for delivering best practice assessment, treatment and management of pain.

SUMMARY

The Guild notes the TGAs efforts to address the problems relating to opioids in Australia and accepts that its options are somewhat limited because it must act within its powers outlined in the Therapeutic Goods Act.

The Guild believes that a nationally co-ordinated real time monitoring system is an essential element of the broad strategy to deal effectively with opioid abuse and misuse in Australia. However we hope that this discussion paper and our suggestion of a follow-up Opioids Roundtable meeting will bring together all stakeholders so that they can do whatever is in their respective powers to solve the problems of opioids in Australia.

Option 1: Consider the pack sizes for Schedule 8 opioids

For consideration

• **The option**: Require sponsors to register and make available for supply both smaller (such as maximum three-day) pack sizes for treatment of patients with acute pain and suitable pack sizes (14 or 28-day) for treatment of people with chronic pain due to malignancy.

• **Potential implementation**: If agreed, these changes may be able to be implemented using powers through either or both the scheduling and/or the registration process.

Guild Response

The Guild believes that changing the marketed pack size does not have an appreciable effect on prescribing habits as the prescriber can order any quantity irrespective of the size of the pack marketed by the sponsor.

There is no compulsion to write a prescription consistent with the pack sizes supplied by a sponsor and community pharmacy is accustomed to breaking original packages or dispensing multiple packs to accommodate the quantity ordered by the prescriber. The Guild believes that in practice requiring the sponsor to register and make available smaller pack sizes will have little practical impact on practice as this is not a strong determinant of prescribing. The quantity of a medicine prescribed can be influenced by a number of factors one of which is the PBS listing status of a medicine, the manufacturer's pack size as well as the intended length of treatment and dose.

The Guild believes there are two issues to consider:

1. The pack size supplied by the manufacturer for non-PBS items. This will be reflected as the "default" quantity in the prescribing software which can easily be overridden by the prescriber if they consider a larger quantity is required.

   Likewise, the default for the number of repeats (which will be zero for non-PBS items) can be increased if the prescriber wishes to order one or more repeats. There is no 'maximum quantity" or "maximum number of repeats" for a non-PBS item.

   As non-PBS items are paid for in full by a consumer (who may or may not receive a reimbursement if they have private health insurance) the quantity of medicine prescribed may be influenced by the consumers' willingness or ability to pay. In some cases it may be more economical to have larger quantities dispensed as the price will be less expensive per dose of medicine.

2. The PBS Maximum Quantity and Repeats for PBS items. This will be reflected as the "default" quantity in the prescribing software for PBS items. Advice from Guild members suggests that it is rare that prescribers order LESS than the PBS maximum quantity even though the PBS "Information for PBS Prescribers" states that:

   > *"PBS prescriptions and repeats can be for any quantity up to the maximum. It is not necessary to prescribe the maximum quantity if a lesser quantity is sufficient for the patient's needs. Please clearly indicate the number of tablets, capsules, etc. required and the number of repeats needed, and* ***do not use*** *abbreviations such as 'Max. Qty', 'M.Q.', or 'M.R.'.*[7] *"*

[7] http://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_2_Explanatory_Notes#Preparing-general-PBS-prescriptions

This issue of Max Qty and Repeats is often raised in the context of antibiotic stewardship with periodic calls by some stakeholders that default PBS quantities and repeats in prescribing software be changed so that a prescriber has to order exactly the quantity of antibiotic required to lessen the chances of antibiotic resistance in the community.

The PBS restrictions may have an influence on prescribing behaviour but this depends on the cost of the medicine. For example, for the recently listed hepatitis C medicines the cost is prohibitive for consumers to bypass any PBS-restriction and have a "private" prescription written and dispensed. For other PBS-listed medicines where the cost of the medicine is less than the Patient Co-Payment a PBS-restriction may have no effect on a consumers willingness to pay for a "private" prescription as there is little to no PBS subsidy.

Example 1

The Guild notes the option to change a pack size has been used by the TGA in response to the concerns with zolpidem (indicated for Insomnia in adults -short-term use, and not PBS-listed). On 21 February 2008[8] the TGA announced that in addition to a boxed warning in the product information documents for zolpidem, the pack size had been reduced *"to encourage only short term use"*. Whilst it is true that most prescribing software defaults to the sponsor's pack size there is nothing to prevent the ordering of multiples of a pack size or any quantity the prescriber chooses. Given that zolpidem is not PBS listed the patient will be paying the full cost of the medicine and therefore the decision could be based on clinical considerations as well as the patient's willingness to pay. In some cases the higher the quantity on the prescription the cheaper the cost per dose.

The Guild's consultation with members would suggest that there is not an appreciable decrease in the use of zolpidem with the reduction in pack size as prescriptions have a quantity for multiples of 14 and in many cases a number of repeats. Our consultations with members suggest that approximately 60% of prescriptions are for 14 tablets, 20% for 28 tablets with 13% for quantities greater than 28. Members reported that approximately 45% of zolpidem prescriptions included a repeat of 1 or more.

Example 2

A similar experience with a change of pack sizes shows the impact on prescribing habits. The PBS maximum quantity of controlled release oxycodone preparations increased in April 2011 from 20 to 28. The maximum quantities of controlled release morphine preparations increased in May 2011. Items with a maximum quantity of 10 were increased to 14 and items with a maximum quantity of 20 were increased to 28[9]. Whilst this was not the only reason that the total use of opioids have continued to increase it must be accepted as a contributing factor.

We believe that the prescribing software default quantity has an effect on prescribing habits but it does depend on the PBS status of the medicine and even then the amount of PBS subsidy that the medicine attracts, if any. The less expensive a medicine is, the less effect any PBS restriction has because there is no price signal to the prescriber and/or consumer.

The Guild believes that changing the pack size has less effect than changing the PBS Max Quantity. However changing the Maximum Quantity of a PBS listed item that attracts a negligible PBS subsidy has very little effect on the quantity prescribed because prescribers/patients can elect to access medicines as private prescriptions. As Price Disclosure decreases the prices of PBS listed medicines more and more items are listed on the PBS at a price less than the General Patient Co-Payment. Also with the increase

[8] https://www.tga.gov.au/media-release/medicine-regulator-places-boxed-warning-stilnox
[9] http://www.pbs.gov.au/info/industry/listing/participants/public-release-docs/opioid-analgesics-overview

each year of the Patient Co-Payments and Safety Net Thresholds fewer consumers reach the Safety Net so it becomes less attractive to record prescriptions on the Safety Net if it is unlikely that it will be reached in the calendar year.

The Guild suspects that the PBS Max Quantity default in prescribing software will dictate the quantity prescribed more so than the manufacturers' pack size. Whilst a prescriber does not have to write a prescription as a PBS benefit and can convert it to a private prescription the software will still default to the PBS Max Quantity unless it is overwritten.

Option 2: Consider a review of the indications for strong opioids

For consideration

• **The option:** The TGA will review indications for the S8 opioids and align them to current clinical guidelines for appropriate prescription of these products.

• **Potential implementation:** This could be done following review of Cochrane and other reviews and meta-analyses of clinical data on opioid efficacy, assessment of therapeutic guidelines for pain treatment and through a standard consultative TGA process. It would require changes to the PI for the products where required (see sections 9D and 25AA of the *Therapeutic Goods Act 1989*). The TGA does have the necessary legal powers to enforce safety-related PI changes.

Guild Response

The Guild agrees that as a matter of consistency it may be beneficial to review the indications for scheduled 8 opioids to align them with the current clinical guidelines but were of the understanding that the indications must be consistent with the data provided to the TGA as part of the registration dossier. Whilst it may be desirable to have consistency across different products so that they align with the clinical guidelines this may not be possible if the dossiers do not contain the necessary data to justify a particular indication.

The Guild has tabulated a number of PBS listed medicines with their corresponding TGA-indication sourced from the TGA approved Product Information (see below). We do not believe that there is a great deal of variation in the wording of the TGA indications that would have any practical impact if they were to be modified to be aligned to current clinical guidelines. We note in one example the wording *"Except in patients with terminal conditions, use of Anamorph should be restricted to short term administration"*. We do not have any data to suggest that this particular product is used differently because of this extra note in the TGA Approved Indication. However, the Guild would reserve our judgement until the TGA has provided a suggested list of re-worded indications and how these would align with clinical guidelines.

Generic	Brand Name	TGA Indication
codeine phosphate hemihydrate 30 mg tablet	Fawns and McAllan Proprietary Limited	Codeine Phosphate 30 mg tablets are indicated for the relief of mild to moderate pain.
hydromorphone hydrochloride 2 mg tablet multiple strengths	Dilaudid	Dilaudid preparations are indicated for the relief of moderate to severe pain.
morphine sulphate	Anamorph	Relief of severe pain (medical and surgical) where non-narcotic analgesics and other measures do not provide satisfactory relief. Except in patients with terminal conditions, use of Anamorph should be restricted to short-term administration.
morphine hydrochloride 20 mg/mL injection, 5 x 1 mL ampoules	Morphine Juno	Morphine hydrochloride is indicated for the following. The relief of moderate to severe pain not responsive to nonopioid analgesics. Symptomatic relief of severe and intractable pains of various categories, in terminal cancer patients. Use as a preoperative medication and as an analgesic adjunct in general anaesthesia.
oxycodone 30 mg suppository, 12	Proladone	Semisynthetic narcotic analgesic. Relief of postoperative pain following a wide range of major operative procedures such as major orthopaedic, abdominal, gynaecological and thoracic surgery, and for the relief of pain in malignant disease.
oxycodone hydrochloride 5 mg tablet, 20	Endone Mayne Pharma Oxycodone IR Oxycodone Aspen	Relief of moderate to severe pain.
oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL	OxyNorm Liquid 1mg/mL	The management of opioid responsive moderate to severe pain.
oxycodone hydrochloride 5 mg capsule, 20	OxyNorm	The management of opioid responsive moderate to severe pain.
oxycodone hydrochloride 10 mg modified release tablet, 28	Novacodonea OxyContina Oxycodone Sandoz	The management of moderate to severe chronic pain unresponsive to non-narcotic analgesia
oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg modified release tablet, 28	Targin 15/7.5mg	The management of moderate to severe chronic pain unresponsive to non-narcotic analgesia. The naloxone component in a fixed combination with oxycodone is indicated for the therapy and/or prophylaxis of opioid induced constipation. Second line symptomatic treatment of patients with severe to very severe idiopathic restless legs syndrome after failure of dopaminergic therapy.
fentanyl 25 microgram/hour patch, 5	Denpax Durogesic	Durogesic is indicated in the management of chronic pain requiring opioid analgesia.
fentanyl lozenge 200 micrograms (as citrate), 9	Actiq	Actiq is indicated for the management of breakthrough cancer pain in patients with malignancies who are already

		receiving and are tolerant to opioid therapy for their underlying persistent cancer pain.
fentanyl 75 microgram/hour patch, 5	Fenpatch 75 Dutran 75	Management of chronic pain requiring opioid analgesia.
fentanyl 25 microgram/hour patch, 5	APO-Fentanyl Durogesic 25 Fentanyl Sandoz	Durogesic is indicated in the management of chronic pain requiring opioid analgesia.
methadone hydrochloride 10 mg tablet, 20	Physeptone	Physeptone is a suitable analgesic in conditions where morphine would make a reasonable alternative, particularly for the relief of pain of visceral origin. It is not recommended for use in ambulant patients.
methadone hydrochloride 5 mg/mL oral liquid, 200 mL	Aspen Methadone Syrup	Aspen Methadone Syrup is indicated for the treatment of dependence on opioid drugs; the treatment of severe pain.
buprenorphine 40 microgram/hour patch, 2	Norspan	Management of moderate to severe pain.
tapentadol 200 mg modified release tablet, 28	Palexia SR	Palexia SR is indicated for the management of moderate to severe chronic pain unresponsive to non-narcotic analgesia.

Option 3: Consider whether the highest dose products should remain on the market, or be restricted to specialist / authority prescribing

For consideration

The option: Review the place of the higher dose S8 opioid products in the management of chronic cancer and non-cancer pain and whether certain high dose products should continue to be registered. We would consider if specific controls, such as approval to prescribe through states and territories or the PBS should be introduced.

Potential implementation: The TGA could undertake a safety review of the benefit/ risk ratio for higher dose S8 opioid products but data is likely to be confounded due to different chronic pain populations (cancer versus non-cancer pain) and opioid tolerance.

Alternatively specialist-only / authority prescribing could be specified for PBS reimbursement, noting that this would not impact on private prescriptions (these could be potentially managed through state and territory regulations).

Guild Response

Whilst the Guild agrees that it may be worth reviewing the higher dose schedule 8 opioid products in the management of chronic cancer and non-cancer pain to justify their continued registration it would not necessarily prevent the prescription of such medicines if the prescriber simply ordered a larger quantity of a lower dose opioid to match the dose of the de-registered product. It may well be that the higher doses were registered in response to market demand and not a cause of it.

It may not necessarily be the availability of a high dose product that results in dose escalation but rather consumer demand and prescribing practices that may have a greater impact. A high dose can simply be ordered using multiple quantities of a low dose product. The PBS even allows prescribers to request an increased maximum quantity and/or increased maximum repeats to accommodate this. In addition, as mentioned elsewhere in our submission, the PBS restrictions on prescribing of medicines for which there is little to no subsidy does not necessarily dictate clinical practice as the prescriber can simply write a private prescription if the consumer is willing to pay.

The prescribing of schedule 8 opioid is managed by the State and Territory Health Departments and most state and territory prescribers need to seek authority to prescribe these substances. For example in NSW the Ministry of Health issues authorities to medical practitioners to prescribe drugs of addiction for chronic pain[10].

An authority from the Ministry of Health is required to prescribe or supply a drug of addiction for:

1. a drug dependent person
2. a non-drug dependent person who is prescribed or supplied with the following drugs of addiction continuously for more than 2 months:
    - any injectable form of any drug of addiction
    - any drug of addiction for intranasal use, or for spray or application to mucous membranes
    - alprazolam
    - buprenorphine (except transdermal preparations)
    - flunitrazepam
    - hydromorphone and methadone

[10] http://www.health.nsw.gov.au/pharmaceutical/doctors/Pages/Prescribe-S8-opioid.aspx

Option 4: Strengthening Risk Management Plans for opioid products

For consideration

The option: Review current risk management plans for opioids to determine whether they currently reflect best practice in opioid prescribing and management of risks.

Potential implementation: Work with sponsors to update their Risk Management Plans (RMPs) to minimise risks associated with overdose, misuse and abuse.

Guild Response

The Guild agrees that a review of the current risk management plans for opioids would be warranted but questions how this would affect prescribing practices.

The Guild notes that in the *"Risk Management Plans for Medicines and Biologicals – Australian Requirements and Recommendations"*[11] the following:

> ## Examples of activities or interventions that may be included
>
> Various activities may be considered, for example:
>
> - ***Additional pharmacovigilance activity*** - an observational cohort study to further identify the occurrence of adverse events that were equivocal or not observed during pre-marketing trials. Although not detected during product development, they may be associated with the class of medicine, and therefore represent a potential safety concern.
>
> - ***Risk minimisation activities*** - beyond the routine these may include communication programs, such as providing educational material to prescribers or performing specific tests. For instance, where a medicine is suspected to be teratogenic, there may be a requirement to perform a pregnancy test prior to prescription, and to ensure adequate contraception.
>
> Any additional risk minimisation activity needs to include a detailed outline of how the effectiveness of the activity to minimise the risk will be evaluated. Examples of measures to assess this include:
>
> - cross sectional surveys with results evaluated against established criteria
>
> - post-authorisation studies
>
> If an educational program is accredited with a learned college, this usually includes/provides an acceptable measure of effectiveness of risk minimisation activity.
>
> Guidance on the measurement of the effectiveness of additional risk minimisation activities is in EMA/204715 Guideline on good pharmacovigilance practices - *Module XVI– Risk minimisation measures: selection of tools and effectiveness indicators*.

With respect to opiate prescribing the Guild would reserve its judgement until such time as the TGA provided a list of suggested inclusions it would consider appropriate for Risk Management Plans for opiate medicines.

[11] https://www.tga.gov.au/sites/default/files/risk-management-plans-for-medicines-and-biologicals.pdf

Option 5: Review of label warnings and revision to the Consumer Medicines Information

For consideration

The option: Under this option, warnings could be placed on the packaging of opioid products identifying the risk of dependence and overdose and lack of efficacy in the long term treatment of chronic non-cancer pain, noting that the complexity of appropriate management of chronic non-cancer pain needs to be recognised. The CMI would also be reviewed to provide greater emphasis on risks of dependence, especially those associated with high doses.

Potential implementation: This may be able to be achieved through modification to the current Therapeutic Goods Order around prescription medicines (TGO 91), although changes to appendices to the Poisons Standard (Scheduling) and to conditions of registration of new strong (S8) opioids could also underpin this requirement. We would need to work with sponsors to obtain CMI changes. It would need to be determined whether S4 opioids such as tramadol would be included in this scheme.

Guild Response

Whilst the Guild does not disagree with this suggestion we believe that this measure may have the potential to send mixed messages to the consumer and could cause unnecessary alarm or distress e.g. if a patient is stabilised on a particular therapy that they believe is working they may be alarmed to read a new warning label on their medicine. On the other hand studies show[12],[13] that consumers may not read or take notice of the warnings on their medicines or CMI and given the low health literacy of the population this many not be an effective way to get the message to the consumer.

The Consumers Health Forum has stated in its Consumer Health Care Priorities for 2018" that *"Too few Australian consumers have sufficient access to the information they need to make well informed choices about their health and care. If we are to strengthen our health system we must address the low levels of health literacy in our community."*

Whilst it is commendable to improve CMI for these medicines the Guild would agree with the CHF that "the low level of health literacy in our community must also be addressed". One way this could be addressed is by the implementation of a Pain MedsChecks program where consumers can have a one on one discussion about their pain medicines with their local community pharmacist. Under the Pain MedsCheck program, pharmacists will assist patients who are taking medication to deal with on-going chronic pain of three or more months, and will evaluate a patient's medicine and the pain management program, ensuring it is supporting their clinical need and providing the best support. It will involve professional pharmacist face to face consultations with patients to review their medication and analgesic use and develop a written action plan, incorporating education, self-management and referral to doctors or other experts where additional support is required. Community pharmacies participating in the program will build relationships with GPs and other health professionals who support patients with chronic pain.

[12] http://www.tandfonline.com/doi/abs/10.1080/13669877.2016.1223160?journalCode=rjrr20
[13] https://www.consumerreports.org/cro/2011/06/can-you-read-this-drug-label/index.htm

Option 6: Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes

For consideration

The option: Provide priority review to new chemical entities that are viable alternatives to opioids for pain relief and also expedite the review of smaller pack sizes and/or abuse-deterrent formulations and products that can be used to negate the effect of opioids.

Potential implementation: This would be responsive to submissions received from sponsors of products and utilise the current regulatory framework.

Guild Response

The Guild would recommend caution in providing priority review of any new chemical entities if this has the possibility to lead to a decrease in the effective assessment of the safety and effectiveness of the reviewed medicine. We believe that what consumers want is access to medicines that have been assessed by the regulator to be safe, effective and of the highest quality. It would be problematic if new chemical entities were rushed through the approval process and later found to be ineffective or worse dangerous. What consumers do not want is a repeat of the rofecoxib[14] or lumiracoxib[15] recalls where the TGA registration of these medicines was cancelled on the basis of safety concerns. Caution should be the first consideration and whilst it would be gratifying to think that patients suffering from pain might have more timely access to new medicines it should not be at the cost of the proper and diligent assessment of these medicines for safety and quality.

Abuse Deterrent formulations

The Guild supports any measures that reduce the abuse and misuse of pharmaceutical opioids which may include such initiatives as abuse deterrent formulations. However, we note that a recently published study[16] found that formulation of controlled-release oxycodone reduced tampering with pharmaceutical opioids among people who inject drugs, but did not affect population-level opioid use or harm. The researchers found reduced sales of higher strengths of controlled-release oxycodone and increased sales of other oxycodone formulations. The availability of a tamper resistant formulation of oxycodone was disappointing and does not provide much confidence that the development of more tamper resistant formulations will address the issues of abuse and misuse.

[14] https://www.tga.gov.au/product-recall/vioxx-rofecoxib

[15] https://www.tga.gov.au/alert/lumiracoxib-prexige-urgent-advice-regarding-management-patients

[16] http://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(18)30003-8/fulltext?elsca1=tlpr

Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong opioids

For consideration

The option: Powers under medicines scheduling could potentially include controls of prescribing for particular populations or classes of medical practitioners, additional safety directions or label warning statements, specific dispensing labels.

Potential implementation: Delegate decision, following public consultation and advice from the Advisory Committee on Medicines Scheduling on additional controls.

Guild Response

The Guild notes that there is currently an Appendix D which includes additional controls such as:

> **Poisons available only from or on the prescription or order of an authorised medical practitioner**
>
> This includes such medicines as clomiphene, clozapine, teriparatide
>
> **Poisons available only from or on the prescription or order of a specialist physician or a dermatologist and for which the prescriber must, where the patient is a woman of child-bearing age:**
>
> > **Ensure that the possibility of pregnancy has been excluded prior to commencement of treatment .**
>
> This includes such medicines as acitretin, etrietinate, isotretinoin or thalidomide

The Guild does not see a benefit in having strong opioids in an Appendix such as the above as we believe that Schedule 8 is for all intents and purposes its very own “Appendix D”. Schedule 8 includes all substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence. Each State and Territory already includes special requirements in their respective Poisons Legislation for schedule 8 medicines and whilst they differ slightly from jurisdiction we do not believe that inclusion of opiates in an Appendix will provide any further controls that could not be done within the current regulatory framework.

We would also note that as State and Territory Health Departments do not have a system to monitor any of the medicines currently listed in Appendix D such as the PBS Online system there is no mechanism to monitor or police the requirements of the Appendix. We note that PBS Online will perversely process a payment for a medicine even if written in contravention to the requirements of Appendix D. This is because the Department of Human Services operates under the *National Health Act* and does not have the legislative responsibility or ability to enforce State and Territory Poisons Legislation.

Option 8: Increase health care professional awareness of alternatives to opioids (both Schedule 4 and Schedule 8) in the management of chronic pain

For consideration

The option: Existing clinical guidelines for the management of acute and chronic pain provide advice on the use of non-pharmacological and alternate pharmacological therapies for the management of pain. While these are available there may be limited health practitioner awareness and uptake.

Potential implementation: The TGA will work with the NPS MedicinesWise and clinical colleges to increase awareness of health practitioners and the uptake of appropriate pain management guidelines in their practices. This could include developing a comprehensive repository of information about the appropriate use of both S4 and S8 opioids. This could use the active networks established under the Nationally Coordinated Codeine Implementation Working Group.

Guild Response

The Guild agrees that there are always opportunities to increase practitioners' awareness of clinical guidelines and this could be done using the CPD requirements of the national boards.

The Guild's Learning and Development's myCPD online learning management system allows pharmacists to further their knowledge and fulfil their professional development and CPD refresher training requirements in one easy to use platform.

The myCPD platform could develop CPD educational modules for pharmacists on professional awareness of alternatives to opioids in chronic pain if required.

The Guild has over 25,000 pharmacists registered on the myCPD site and have delivered over 104,000 courses/assessments to pharmacists in the past CPD year.

For the recent codeine up scheduling the Guild, in conjunction with the Pharmaceutical Society of Australia, developed and made available six modules for pharmacists that cover such topics as:

- Managing the transition to Prescription Only Medicines
- A Patient focused Clinical Overview of Pain
- Transforming your business
- Pain Management in practice
- Principles of pain management
- Communication in pain management

Guild Learning and Development is also developing educational modules on de-identified case studies involving misuse of prescriptions medications with a view to providing continuing education to pharmacists in identifying and responding to prescription shopping and/or drug dependency. This follows the recommendation from the NSW Coronial Inquest into four deaths involving a number of scheduled medicines and misadventure.

Possible role of Pharmaceutical Benefits Scheme prescribing controls

There may also be additional options to better manage opioid prescribing through the PBS. For example, in response to concerns about the significant growth of prescriptions for testosterone in men, PBS restrictions on prescribing were introduced during 2015. A requirement for a specialist review prior to prescription and lowering of the threshold serum levels for testosterone deficiency resulted in the proportion of men getting a prescription in the absence of pathological hypogonadism decreased significantly.[17]

Controls such as narrowing the group of approved prescribers (for example certain specialists) and requiring a telephone authority can also impact on the number of prescriptions for a particular medicine as they require consideration by the prescriber as to whether the prescription meets the requirements for reimbursement.

It is possible that similar PBS prescribing restrictions could have an impact on unsanctioned strong opioid use, although many S8 opioids now fall below the co-payment level for non-concessional patients – for example oxycodone 5-20 mg immediate release products are between $20-28 on private prescription.

However, even if private prescription prices are comparatively low, PBS restrictions can cause a prescribing physician to reflect on choice of medicine. It should also be noted that concessional patients are prescribed a disproportionate amount of S8 opioids, especially for the more expensive extended release products. This will also require consultation with the PBAC.

Guild Response

The PBS is a subsidy scheme that started in 1948 to provide a limited number of life-saving and disease preventing medicines for the community. As noted on the Department's PBS website *"Today the PBS provides timely, reliable and affordable access to necessary medicines for Australians. The PBS is part of the Australian Government's broader National Medicines Policy. The aim of the National Medicines Policy is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved. Under the PBS, the government subsidises the cost of medicine for most medical conditions. Most of the listed medicines are dispensed by pharmacists, and used by patients at home. Some medicines are dangerous to administer and need medical supervision (such as chemotherapy drugs) and are only accessible at specialised medical services, usually hospitals."*

The Guild does not believe that the PBS as a subsidy scheme is the appropriate nor the most effective mechanism to better manage opioid prescribing. Whilst the price a patient pays for their medicine may have an impact on the behaviour of a prescriber and the consumer most of the opioid medicines listed on the PBS are less than the General Patient Co-Payment. An analysis of the PBS schedule and usage data from Department of Human Services show that almost 50% of PBS listings for opiates have a Dispensed Price for Maximum Quantity (DPMQ) of less than the General Patient Co-Payment of $39.50. These PBS listings represented 80% of opioid items dispensed as PBS items in the 2016-17 financial year. Even in cases where the medicine may be relatively expensive and above the patient co-payment there is nothing to prevent a prescriber writing a private prescription for a particular consumer who may be happy to forgo a government subsidy or a contribution to the PBS Safety Net threshold.

We would also note that the Department of Human Services operates the Prescription Shopping Programme (PSP)[18], which can identify whether a patient is potentially being oversupplied. However

[17] www.6minutes.com.au/News/Latest-news/GP-testosterone-scripts-plunge

[18] https://www.humanservices.gov.au/organisations/health-professionals/services/medicare/prescription-shopping-programme#a1

there are many limitations to the program which makes it ineffective in dealing with misuse and abuse of opiate medicines.

As detailed on the Medicare website a potential 'prescription shopper' is identified as someone who, in the past 3 months, has had one of the following:

- prescribed pharmaceutical benefits by six or more different prescribers
- received 25 or more target pharmaceutical benefits
- received 50 or more pharmaceutical benefits.

The PSP cannot tell a prescriber if:

- samples of medication have been provided to your patient by a prescriber
- private prescriptions have been supplied
- over the counter medicine has been used by your patient
- any emergency treatment has been provided to your patient by a prescriber
- emergency PBS medicine has been supplied by a pharmacist
- medicine is prescribed under the RPBS, or
- it is the supply of section 100 medicines.

The Guild notes the example of testosterone as a PBS benefit and how after a change in the PBS listing a decrease was seen in the number of PBS prescriptions dispensed. However as the DUSC report also notes:

> ***"There was a shift in the proportion of private to PBS-subsidised testosterone prescriptions written in the year after the restriction change, according to MedicineInsight data. Prior to 1 April 2015, an average of 21% of prescriptions was private. This number increased to an average of 43% after the change.[19]"***

As the Department of Human Services does not collect data on the non-PBS prescriptions dispensed it is not possible for a true assessment to be made as the MedicineInsight data does not reflect the dispensing of all private prescriptions for testosterone. MedicineInsight data is extracted from the clinical information systems that participating general practices use to manage patient records and write prescriptions[20]. Whilst it might appear that this is an effective strategy it may simply shift costs from the PBS to the private market. In fact given the competitive nature of the community pharmacy landscape it can often be cheaper to have a PBS medicine dispensed as a private prescription and many discount pharmacy banner groups advertise the private prescription price on their websites.[21]

As mentioned earlier the Guild suggests that the TGA urgently review the *Price Information Code of Practice*. This code allows for the publishing of price lists of medicine but we would question if it is appropriate to promote the availability of larger quantities of medicines that are liable to misuse, abuse or addiction. The Guild believes that a new Therapeutic Goods Advertising Code which limits the risk of medicines advertising/price information which is inconsistent public health messages needs to be developed. We believe that the price promotion of medicines that could be misused, abused or have the potential for addiction should not be allowed.

[19] http://www.pbs.gov.au/info/industry/listing/participants/public-release-docs/dusc-public-release-documents-by-meeting Sept 2016
[20] https://www.nps.org.au/medicine-insight/using-medicineinsight-data
[21] http://www.chemistwarehouse.com.au/buy/42907/Androderm-5mg-24hr-Patch-30-28A29