PENINGTON INSTITUTE

Submission to the Therapeutic Goods Administration's consultation paper

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

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About Penington Institute

Penington Institute, a not-for-profit organisation, advances health and community safety by connecting substance use research to practical action.

We support individuals and the wider community through research analysis, promotion of effective strategies, workforce education and public awareness activities.

Penington Institute first formed two decades ago as Anex (now a program of Penington Institute) — a network of service providers to prevent HIV/AIDS transmission related to unsafe injecting drug use.

Since then, Penington Institute has been responding to the emerging evidence-base and practice wisdom in the field of public health.

Introduction

Penington Institute welcomes the opportunity to comment on the Therapeutic Goods Administration's consultation paper on prescription strong (schedule 8) opioid use and misuse in Australia and options for a regulatory response. The misuse of opioids is a growing problem in Australia, between the years 2011 and 2015, 3601 people died from an accidental prescription opioid overdose, a 1.6-fold increase from 2001 to 2005.[1] Measured regulatory changes should be considered in order to save lives and reduce harm.

The Underlying Problems with Opioid Use

Opioid dependence is a complex health condition that affects people from all walks of life, including those who have become addicted to prescribed pain relievers. Any new strategies for preventing people becoming dependent on prescription opioids need to be carefully assessed. Restricting or withdrawing access to these drugs does not of itself solve or address underlying problems that have led to someone using prescription based opioids. If a person has a strong prescription opioid use problem, they may seek other avenues to obtain opioids if they cannot access prescription drugs such as oxycodone, codeine etc. This may include acquiring prescription drugs via the black market or turning to illicit opioids like heroin. This brings with it a range of harms including an increased risk of blood-borne viruses, unsafe injecting practices, along with stigmatisation and even criminal activity to fund their drug use.

Evidence from the United States suggests that regulatory changes could potentially provide a boost to the black market, given how far people are willing to go to seek out opioids to avoid withdrawal. States in the United States, such as Kentucky and Ohio, have instituted measures intended to limit opioid abuse and the unintended consequence has been an increase in heroin use.[2] When examining efforts to reduce wide-scale abuse of oxycodone via an abuse-deterrent formulation released in 2010,[3] researchers spoke to people from 150 public and privately funded treatment centres in 48

[1] Penington Institute, (2017), "Australia's Annual Overdose Report 2017", Melbourne.
[2] Theodore J. Cicero, Matthew S Ellis, (2015), "Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from Oxycontin", *JAMA Psychiatry*, 72(5): 424-429.
[3] People using opioid drugs for recreational purposes often chew the pill to release the drug or more commonly crush it for inhalation or create a solution for injection. The goal of abuse-deterrent formulations is to make the pills very difficult to crush or chew; hence combating non-therapeutic use of the drug.

states. 51 of the respondents indicated that the introduction of the abuse-deterrent formulations led them to shift drug choices, with 70 per cent changing to heroin.[4] Just one individual from the 150 participants switched to a non-opioid drug. Researchers concluded that an initial decline in oxycodone abuse was related to a shift to other opioids, most notably heroin.[5]

Treatment Services in Australia

Regulatory changes to restrict access to opioids can't be viewed in isolation from the status of treatment services in Australia. Treatment services are under great pressure in many parts of Australia. In 2014, the National Drug and Alcohol Research Centre stated that unmet demand for alcohol and drug treatment is conservatively estimated to be between 200,000 and 500,000 people.[6]

What is required in addition to changes to regulatory rules, is greater availability of treatment services across Australia and a wider range of clinical pathways that are flexible, adaptive and assessable to people within their community.

The Benefits of Pharmacotherapy (Opioid Maintenance Therapy)

Pharmacotherapy is an effective medical treatment to reduce people's use of heroin or other addictive opioid-based drugs such as OxyContin and Fentanyl. It is an evidence-based, cost-effective public health strategy for managing opioid dependence.[7] One factor which needs to be considered in the context of prescription opioid use in Australia is the dispensing fees for pharmacotherapy (opioid maintenance therapy), such as methadone or buprenorphine.

The World Health Organisation has declared buprenorphine and methadone as essential medicines that can significantly improve and save lives.[8] It has classified them as medicines which people should have access to at all times and in sufficient amounts. The benefits are well documented, with studies showing a reduction in illicit drug use and an improvement in health and wellbeing when people dependent on opioids are maintained on a daily dose.[9]

Evidence demonstrates that pharmacotherapy also reduces the rate of criminal activity in the community,[10] reduces overdoses,[11] prevents the spread of blood-borne viruses[12] and assists people to stabilise their lives,[13] which helps them to lead more productive lives.

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[4] Cicero, Ellis, 2015 op cit.
[5] Ibid.
[6] Alison Ritter, Lynda Berends, Jenny Chalmers, Phil Hull, Kari Lancaster and Maria Gomez, (2014), "New Horizons: The review of alcohol and other drug treatment services in Australia", National Drug and Alcohol Research Centre.
[7] Dolan K; Alam Mehrjerdi Z, (2015), "Medication-assisted treatment of opioid dependence a review of evidence", Australian National Council on Drugs, Canberra, ANCD research paper 32.
[8] WHO Expert Committee on the Selection and Use of Essential Medicines, (2006), ttp://www.who.int/medicines/publications/essentialmeds_committeereports/TRS946_EMedLib.pdf.
[9] Feyer, A. Mattick, R., Schulman, C., Jessop, R., Soloman, J. & Pyper, D. (2008). A National Funding Model for Pharmacotherapy Dependence in Community Pharmacy. Sydney, NSW: Department of Health and Ageing, The Pharmacy Guild of Australia, National Drug and Research Centre, Price Waterhouse Coopers.
[10] Bukten, A., Skurtveit, S., Gossop,M., et al, (2012), Engagement with opioid maintenance treatment and reductions in crime: A longitudinal national cohort study. *Addiction* 107(2), 393-399.
[11] Pierce, M., Bird, S. M., Hickman, M., & Millar, T., (2015), "National record linkage study of mortality for a large cohort of opioid users ascertained by drug treatment or criminal justice sources in England, 2005– 2009. Drug and Alcohol Dependence,146, 17-23.

The demand for pharmacotherapy in Australia continues to increase. There were 2,556 prescribers in Australia in 2015 - a nine per cent increase from 2014 - and a constant demand remains for the program to expand.[14] Community pharmacists provide the majority of dosing points (2,589 in 2015), with many more community pharmacists reluctant to offer the service.[15]

Retaining people on opioid substitution is a well-documented challenge.[16] As detailed in a recent Penington Institute discussion paper C*hronic unfairness: equal treatment for addiction medicines?*[17] there are major obstacles to enabling more Australians to access medication-assisted treatment and to maintain that treatment.[18]

Dispensing fees are arguably the single greatest impediment to retaining people in pharmacotherapy;[19] when provided via a community pharmacist it can cost patients anywhere from $1 to $10 a day.[20] These co-payments have a profound impact and can jeopardise treatment continuity.[21] Even a small daily fee of a few dollars to access methadone leads to greater economic hardship for these patients, many of whom are already under financial stress, and therefore an increased risk of criminal activity. The cost negatively affects quality of life for clients, with many having to opt between missing their regular dose or, going without food, other medications or rent in order to afford it.[22]

For some people it may actually be cheaper to access other pharmaceutical opioids, rather than pharmacotherapy. For example, the cost of oxycodone can be as little as $6 a month and does not necessitate a person visiting a pharmacy every day.[23] Removing fees for pharmacotherapy is something that should be included in any discussion concerning the use and misuse of prescription opioids. Given the widespread benefits of pharmacotherapy, Penington Institute believes that eliminating these fees would make an enormous difference in the context of problematic opioid use.

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[12] White et al, (2014), "Opioid substitution therapy protects against hepatitis C virus acquisition in people who inject drugs", the HITS-c study, *Med J Aust*. 2014; 201(6): 326-329.
[13] Maremmani, I., Pani, P., Pacini, M., et al., (2007), "Substance use and quality of life over 12 months among buprenorphine maintenance-treated and methadone maintenance-treated heroin-addicted patients", *Journal of Substance Abuse Treatment* 33)1), 91-98.
[14] This increase occurred mainly in Victoria and is likely due to the creation of Pharmacotherapy Networks in early 2014 — with one of their main roles being to increase the numbers of providers in Victoria.
[15] Chaar B et al, (2011), "Provision of opioid substitution therapy services in Australian pharmacies", *Australian Medical Journal*, 4, 4, 210-216.
[16] Rowe J., (2007), *A raw deal? Impact on the health of consumers relative to the cost of pharmacotherapy.* Melbourne: RMIT and the Salvation Army.
[17] Penington Institute, (2015) Chronic unfairness: equal treatment for addiction medicines? Melbourne, Australia http://www.penington.org.au/wp-content/uploads/2015/04/Chronic-Unfairness-Penington-Institute.pdf
[18] Ibid.
[19] Rowe 2007 op. cit.
[20] Penington Institute, 2015 op cit.
[21] Ibid.
[22] Rossmanith A, (2011), "Fees for pharmacotherapy: an unfair burden?" *Of Substance*, vol 9 no 3.
[23] Penington Institute, 2015 op cit.

Naloxone in Australia

Any discussion concerning prescription opioid use and misuse needs to consider the important role of naloxone. Naloxone is an opioid antagonist that reverses the effects of opioid overdose when administered in a timely fashion. It has been available in Australia in emergency clinical settings for decades, though access expanded in 2012 with the introduction of the take-home-naloxone program providing the opportunity for a non-medical person to administer naloxone to someone else to treat a potentially fatal overdose.

Naloxone works by displacing an opioid at the level of our brain's neurological receptors; essentially "kicking" the opioids off the brain's receptors. This reverses all the effects of the opioid, including depression of the respiratory system which is the principle danger of opioid overdose. By administering naloxone, a person's breathing can be restored, buying critical time for emergency services to be notified and proper treatment to be administered.

Today, naloxone can be prescribed by a doctor and is also available directly from a pharmacist over the counter (schedule 3), albeit at substantially higher cost than via prescription. Naloxone is currently available in Australia as single-dose glass ampoules or in a prefilled five-dose syringe ("Prenoxad"). Intra-nasal formats of naloxone (administered as a nasal spray) are not currently available in Australia, though they are a key component of state responses to overdose elsewhere.

In response to the crisis of opioid overdose occurring internationally, many other countries have also rescheduled naloxone and implemented programs that expand access to naloxone for affected communities.

The focus for increased access has moved from solely targeting people engaged in street-based opioid injecting who frequent services such as NSPs to include a range of key populations and their interactions with different services/institutions. This expansion is in line with a 2014 World Health Organisation (WHO) recommendation that all "people likely to witness an opioid overdose should have access to naloxone and be instructed in its administration…".[24] The provision of naloxone, with appropriate training, to people (including friends, family, and service providers) who use or come in contact with people who use opioids can lead to successful opioid overdose reversals.

Based on the probability of witnessing an overdose (60 per cent of people who died of an accidental overdose were not alone when they died), three populations for take-home-naloxone programs have been targeted across a range of initiatives and include:

1. People who use opioids, especially those using high-dose pharmaceutical opioids;
2. People who use drugs, including: current opioid injectors; opioid users upon release from prison; former opioid users upon release from detox/rehab; and individuals starting Opioid Maintenance Therapy (OMT);
3. Carers, including family members, friends and other close contacts of people who use drugs. Evidence shows that people in close contact with people who use drugs want training in overdose management and how to administer take-home-naloxone; and
4. Agency staff, including medical settings, healthcare providers and Needle and Syringe Programs (NSPs). Evidence shows mixed levels of support by agency staff in prescribing and administering naloxone.

[24] World Health organization (2014) "Naloxone: A take-home antidote to drug overdose that saves lives": http://www.who.int/features/2014/naloxone/en/.

While there have been changes making naloxone more available, challenges remain with accessing and creating demand for naloxone with people who use opioids. One of the main challenges experienced by service providers and policy makers is how best to achieve sufficient coverage of a growing at-risk population. Even with the likely introduction of intra-nasal naloxone in Australia at some point, this challenge is expected to persist.

Australia's present access arrangements for accessing naloxone have enabled some innovative and effective models of distribution, especially where highly motivated practitioners – "champions" of overdose prevention within both their organisations and communities – have established coordinated arrangements with local pharmacists and doctors. Unfortunately, these models are bespoke, highly reliant on individual actors and generally not scalable.

Convenient and affordable (free) naloxone access needs to be a given; it ought to simply "work". It is telling that countries that have scaled up the use of naloxone in community settings do not make it so difficult to get it into people's hands. Publicly-funded take-home naloxone models now exist, most notably in North America and Europe, whereby naloxone is offered free and by purchase from a range of settings to a range of clients.

By contrast, given naloxone is a high-efficacy, low-risk medicine, Australia's current arrangements for prescribing and dispensing naloxone are unduly complex and restrictive. Asking overdose prevention workers to continuously correct for this complexity is not an efficient use of their time. They would be better deployed deepening their engagement with people at risk of overdose and widening their engagement with key groups of overdose witnesses (such as friends and family). Simplifying naloxone access will facilitate this – and, at the same time, it will give workers a better, cheaper and more convenient naloxone service to offer to their clients. A further improvement would be a greater diversity of naloxone products, including intra-nasal naloxone, in Australia's market – thus providing choice to consumers.

Ontario's Take-Home Naloxone program

One model for scaling up community access to naloxone is through the implementation of take-home naloxone (THN) programs. The THN model introduced in the Canadian province of Ontario is worth due consideration.[25] When the Ontario THN was first launched in 2013, it comprised one program — the Ontario Naloxone Program — which operated out of Needle and Syringe Programs (NSPs) to provide clients of NSPs with take-home naloxone kits. Since then, the program has been expanded significantly, and now comprises three separate though cooperative and complimentary programs.

Importantly, those at risk of opioid overdose do not comprise a single discrete group (such as injecting drug users). Instead, those at risk of opioid overdose are a diverse population with a range of differing needs, levels of engagement and health literacy. The three-tiered structure of the Ontario THN recognises this and, in response, is flexible and accommodating of that demographic diversity. The three tiers model also ensures widespread coverage and high levels of accessibility: the program is not onerous to participate in and demands little of those wanting to access naloxone through it.

[25] Ontario Ministry of Health and Long-Term Care, "Naloxone: Frequently Asked Questions": http://www.health.gov.on.ca/en/pro/programs/drugs/naloxone/naloxone_faq.aspx.

The Ontario model is an instructive case study as it demonstrates several of the key features needed for an effective program of community access to naloxone, such as flexibility, convenience and coverage.[26]

The first tier of the program (the "Ontario Naloxone Program" or "ONP") distributes pre-assembled naloxone kits free of charge through a range of agencies that work with key populations at risk of overdose. The types of agencies able to dispense free kit through this program are needle and syringe programs (including their outreach work), community health centres, homeless shelters, drop-in centres, withdrawal clinics, supervised injecting facilities and HIV/AIDS services.

Clients of these services can request a naloxone kit (containing two doses of intra-nasal naloxone) which they receive free of charge and without having to show any documentation. Agency staff are then able to provide training on recognising an opioid overdose and how to correctly administer the naloxone. In addition, organisations participating in the ONP are authorised to set up temporary "pop-up" overdose prevention sites at identified hotspots without needing approval.

There are currently 54 primary sites operating as part of the ONP. Each primary site coordinates a network of other agencies, all of which are naloxone distribution points. Every municipality in Ontario contains an ONP primary site. Since launching in 2013, 36,200 naloxone kits have been dispensed to clients through the ONP.

The second tier of the program, launched in 2016, is the Ontario Naloxone Program for Pharmacies (or ONPP), which makes THN kits available through participating pharmacies. The cost of kits is covered by the provincial government through a claiming scheme.

Pharmacy participation is voluntary though no sign-up is required, so to participate a pharmacy can simply begin ordering kits and claim the cost for each kit dispensed. Anyone can access a THN kit through the ONPP provided they have a valid Ontario Health (Medicare) card (or are with someone that does). Training is provided by the pharmacist for those who need it. There are approximately 4,400 pharmacies in Ontario and of these, 2,300 participate in the ONPP. To date, 67,500 THN kits have been distributed through the ONPP.

The third tier of the program, also launched in 2016, operates in all 26 of Ontario's correctional facilities. The Correctional Services Take-Home Naloxone (CS-THN) program provides naloxone kits to newly released inmates who are at-risk of opioid overdose. Upon entry to a correctional facility, participation is offered to any inmate who identifies as at risk of overdose. Prison staff then train the inmate in naloxone administration and, upon release, the inmate is provided with a free kit containing two doses of intra-nasal naloxone. They are also given a wallet card with a phone number they can call to locate their nearest naloxone distribution point. To date, 2,200 THN kits have been distributed to newly-released inmates through this program.

Relevance to the Australian context

The range of active distribution points and the number of THN kits dispensed in Ontario demonstrates the high degree of both coverage and uptake achieved by the THN program. What we know following the rescheduling of naloxone in Australia is that even when the availability of

[26] Canadian Pharmacists Association (2017) 'Environmental Scan: Access to naloxone across Canada': https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/Environmental%20Scan%20-%20Access%20to%20Naloxone%20Across%20Canada_Final.pdf

naloxone is increased, greater uptake does not automatically follow. Therefore, awareness and promotion of naloxone will be a key part of any large-scale program in Australia.

While the Ontario model should not be regarded as a panacea to the problem of overdose — as the still growing numbers of overdose deaths across Canada demonstrate — the strengths of the Ontario program highlight many of Australia's weaknesses. The Ontario program is sophisticated, robust and adaptive, covering several key populations through a dispersed network of access points. Unfortunately, Australia does not have one of Canada's key naloxone access points, supervised injecting facilities (aside from one in King's Cross, Sydney and another earmarked for North Richmond, Melbourne). In Ontario, barriers such as cost and participation requirements are low, and there are a diverse range of stakeholders who are actively supported. Coordination and governance are largely centralised, though local infrastructure and partnerships are actively utilised.

The combination of widespread access and low (no) cost is critical for a successful large-scale naloxone program. People who are at risk of overdose are often marginalised and may be experiencing a range of disadvantages, so access barriers like location and cost can mean the difference between accessing and not accessing naloxone. Providing naloxone for free and through access points that are convenient and desirable for those accessing it will be critical in Australia.

Importantly, both injectable and intra-nasal naloxone products are available through the Ontario THN, meaning clients are more able to access the format they prefer.[27] For example, while a long-term intravenous drug user may prefer injectable naloxone, a mother who requests a kit because she suspects her child might be using opioids may be intimidated by the prospect of delivering an injection and prefer the intra-nasal format.

In Australia, clients are restricted to using either glass ampoules or the pre-loaded syringe, both of which involve administering one or multiple injections. To administer naloxone via glass ampoules, the ampoule is snapped open and the medicine is drawn up into a syringe. The naloxone is then delivered via an intramuscular injection into the upper arm or thigh; if a further dose is required then the process is repeated with a fresh syringe. To administer Prenoxad, the pre-loaded syringe is removed from its cover, opened and the desired dose is delivered via injection.

Using glass ampoules and syringes is the most complicated method of administration. This is particularly so in situations of high stress, such as when witnessing an opioid overdose. Prenoxad has some clear advantages over glass ampoules in terms of ease of use, as the medicine is contained in a single unit making opening ampoules and drawing up unnecessary.

However, delivering an injection is something many people are not familiar with and this can be highly intimidating or stressful. With intranasal naloxone, the need for an injection is removed, constituting a significant improvement over both forms of injectable naloxone.

There are anecdotal reports from North America of clients disliking the intra-nasal formats due to the inability to control dosage. Narcan, the intra-nasal naloxone available in North America, contains a very high dosage of naloxone (4mg/1ml). In comparison, a single glass ampoule contains .4mg/1ml, or one-tenth the amount. While there is no risk of causing injury from administering too much naloxone, because the medicine reverses the effects of an opioid a high dose can send someone into sudden opioid withdrawal which is deeply unpleasant.

[27] While the ONP and ONPP only offer intra-nasal and injectable naloxone respectively, both programs are aiming to provide both products so clients can access their preferred format.

Nevertheless, part of expanding access to naloxone is expanding the product range available, to ensure those who need the medicine can access it in a format that they are comfortable with and feel confident using.

Considering the evidence, Penington Institute recommends that Australia rapidly scale-up the availability of naloxone through large-scale community access programs like the one operating in Ontario. In addition to this, Penington Institute would like to see the naloxone product range widened to include intra-nasal naloxone as part of Australia's response to the ongoing public health issue of opioid overdose.

Penington Institute is currently conducting research into different models of naloxone distribution including the Ontario model, and would welcome the opportunity for further discussions with the TGA regarding the feasibility of such programs in Australia.

Assessing the Options for Improving Australia's Opioids Problem

Options One to Three

- **Option 1:** Consider the pack sizes for strong (S8) opioids.
- **Option 2:** Consider a review of the indications for strong (S8) opioids.
- **Option 3:** Consider whether the highest dose products should remain on the market, or be restricted to specialist/ authority prescribing.

Penington Institute thinks that the option of offering smaller pack sizes for people with acute pain and different pack sizes for those with chronic pain is a sensible proposal.

Such a change has occurred in various jurisdictions in the United States, though this is more often in the form of strict prescription limits for various types of conditions. For example, Massachusetts was the first state in the United States to set a seven-day supply limit for first-time opioid prescriptions, a system taken up by many other jurisdictions since.[28] There has also been movement in the private sector in the United States when it comes to prescription amounts. Pharmacy company CVS has announced it will limit opioid prescriptions to seven days for certain conditions.[29]

The model proposed by the TGA of allowing for different pack sizes without legally prescribing which ones can be used for different conditions is a better alternative. Any model that provides greater flexibility in prescribing policies should be encouraged, particularly since patients require prescription opioids for a range of reasons. An individual who has undergone a relatively minor surgery may not necessarily require a 28-unit dose pack of oxycodone, for example. There is compelling evidence that long-term use of opioids to manage conditions such as chronic musculoskeletal pain should be approached with great caution.[30]

Regarding option two, Penington Institute concurs that a review of the indications for S8 opioids to align them with current clinical guidelines for appropriate prescription is a rational proposal. We hold concerns about reviewing whether certain high dose opioid products should continue to be registered in option three. Healthcare professionals should be careful in prescribing opioids with greater morbidity and mortality and risk of diversion and abuse. However, removing these opioids entirely could negatively impact on people who do require these drugs. Although recreational abuse of opioids will always remain a problem, it has been shown that halting the use of opioids can harm people with severe pain.[31] The authors of one study in *The Canadian Journal of Pain* concluded:

> "Fear of addiction should not be the reason for restricting opioids to the many people with chronic pain who benefit and whose quality of life is enhanced by their use."[32]

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[28] William T Pound, National Conference of State Legislatures, (2017), "Prescribing Policies: States Confront Opioid Overdose Epidemic", http://www.ncsl.org/Portals/1/Documents/Health/prescribingOpioids_final01-web.pdf.

[29] Andrew Joseph, (2017), "CVS tightens restrictions on opioid prescription in bid to staunch epidemic", https://www.statnews.com/2017/09/21/cvs-opioid-prescription-limits/

[30] Michael R. Von Korff, (2013), "Long-term Use of Opioids for Complex Chronic Pain", *US National Library of Medicine* 27(5): 663-672

[31] Atkinson TJ, Schatman ME, Fudin J., (2014), "The damage done by the war on opioids: The pendulum has swung too far", *Journal of Pain Research*, 7:265–268.

[32] M. E. Lynch and J. Katz, (2017), "'One Size Fits All' Doesn't Fit When It Comes to Long-Term Opioid Use For People with Chronic Pain", *Canadian Journal of Pain*, 1:1, 2-7.

Also, as noted earlier, any attempt to impede the use of certain opioids may inadvertently encourage some people to seek out illicit alternatives.

Penington Institute welcomes TGA's clarification of 27 January 2018 that there is no plan to limit GP's capacity to prescribe high dose opioids under this review in option three. GPs are, after all, at the frontline of healthcare and encounter a variety of people who need opioids. Designating this responsibility to specialists or authority prescribers could have a series of unintended consequences that will disproportionately impact people living outside of our major cities where the only healthcare professional available may be a GP.

This is especially concerning given that there has been a marked increase in overdose deaths across regional Australia. In 2010, the per capita accidental death rate between metropolitan and regional Australia was similar at 6.0 per 100,000 in the cities and 5.9 in regional areas. But five years later accidental drug-related deaths in regional Australia reached 7.3 deaths people in comparison to 5.8 deaths in metropolitan areas.[33]

Option three raises an important point that Penington Institute thinks deserves far greater attention in any discussion concerning prescription opioids. There is reference to the "wider availability of naloxone" having been suggested and we agree that a greater focus on this life saving drug is vital.

As indicated earlier, naloxone is a remarkable medicine that has few adverse effects and no abuse potential; even if given to someone who is unresponsive for a reason other than opioid toxicity, it is extremely unlikely to cause harm.[34] Given that overdose deaths outnumber road deaths in Australia, it has immense potential to save lives. This is particularly so in rural and regional areas, where long distances mean that ambulance response times are typically slower than in metropolitan areas.

Naloxone needs to be widely accessible and easy to use. Penington Institute has undertaken work to raise awareness about this drug in the broader community, particularly with people who are injecting drugs, their family and friends and other potential overdose witnesses. It is also important to encourage medical professionals, including GPs, to offer naloxone to patients who could benefit from the drug.

Options Four to Six

- Option 4: Strengthening of the Risk Management Plans for opioid products
- Option 5: Review of label warnings and revision to Consumer Medicines Information
- Option 6: Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes

In relation to option four, reviewing current risk management plans for opioids is a good step forward; particularly since most opioid medicines were registered before 2009 when the requirement for such plans were introduced. A stronger focus on health care professional education and training is welcome. When considering the topics that could be provided via an educational program Penington Institute agrees that topics such as the effectiveness of opioids in chronic non-cancer pain sound promising.

[33] Penington Institute, 2017, op.cit.
[34] Marianne E Jauncey and Suzanne Nielsen, (2017), "Community use of naloxone for opioid overdose", *Australian Prescriber*, 40(4): 137-140.

However, we think that opioid educational programs should also include information about naloxone. GPs could, for example, receive information about this drug and the benefits of encouraging people who inject drugs – as well as their friends and families – to access naloxone. GPs could also be urged to teach people how to inject naloxone and give guidance on its use. This includes advising patients that the effects of naloxone will wear off after 30 to 90 minutes and that medical attention should be sought even if the drug has been administered to someone suffering from an overdose.[35]

Option five proposes that warning stickers identifying the risks of opioid dependence and overdose should be placed on the packaging of opioid products and Penington Institute considers this a worthwhile proposal. We also believe that the stickers should refer to the importance of naloxone in temporarily reversing an overdose if one occurs. For example, the warning could state: "In the event of overdose, naloxone should be immediately administered and medical help sought by calling 000."

Penington Institute agrees that the abuse-deterrent opioids referred to in option six hold promise. The combination of the opioid agonist with an antagonist such as naloxone holds particular appeal, because as we have noted much more needs to be done in Australia to encourage the uptake of naloxone to save the lives of people who inject drugs.

This option also mentions new "formulations of antidotes that allow carers to administer antidotes more simply". As indicated, Penington Institute believes that naloxone only being available in injectable format in Australia is something that holds wider use of this drug back.

It is essential that we pursue all avenues to diversify the means by which naloxone can be used in a community setting, from intramuscular injection only to include a nasal spray – sometimes referred to as intra-nasal naloxone. This product, which has been developed in the United States but is not yet registered for use in Australia, could have an enormous impact in Australia if people are made aware of this product and it is widely available.

Options Seven and Eight

- Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong S8 opioids (this could potentially include controls of prescribing for particular populations or classes of medical practitioners, additional safety directions or label warning statements, specific dispensing labels).
- Option 8: Increase health professional awareness of alternatives to opioids (both S4 and S8 opioids) in the management of chronic pain.

In relation to option seven, Penington Institute thinks that there are potential problems with limiting the prescribing of certain opioids to some medical practitioners such as palliative care physicians. These are similar to the points made in relation to GPs in option three. We are broadly supportive of specifying education requirements in the annex to the Poisons Standard; as noted earlier this is a good opportunity to boost training in regard to naloxone administration.

Penington Institute supports the concept of increasing health care professional awareness of alternatives to opioids. Though we emphasise again that there will be challenges associated with de-prescribing or reducing dosages for people who have been on long term opioid therapy.

[35] Penington Institute Fact Sheet: Naloxone Information: http://www.penington.org.au/wp-content/uploads/2017/08/Naloxone.pdf