TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone and do not suggest any further improvements. Many thanks to the individuals who have brought this to the attention of the TGA. Similar changes happened in Europe almost 25 years ago, and this reduced the number of opiate overdose related deaths.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
• I lost a friend to overdose [redacted] Had we had Naloxone on hand his death would have been prevented. We had to wait 12 minutes for the ambulance to come and by then he was dead. If we had naloxone it would have kept him alive for that 12 minutes and then the ambulance staff could have taken over with a live body, not a dead one. • If Naloxone was over the counter, I would buy it. [redacted]. Being able to buy it discreetly in a chemist would increase my access to Naloxone. • I would ask family & friends to keep naloxone at hand 'just in case' [redacted] someone they know has an overdose. • I and the people I know and love are at risk of Overdose and I don't want [redacted] them to die. Easy access to naloxone will significantly decrease this risk. • Prompt use of naloxone is critical and there is often a significant time lapse between reporting an overdose and waiting for an ambulance with naloxone to arrive which increases the risk of fatality or brain damage. Response times can be shortened and lives can be saved. • There is often someone else present during an overdose so it makes sense for them to have naloxone. • People do not want to access naloxone from GP as they will have to disclose their drug use and fear discrimination • Sometimes it can be hard to organise an appointment to the Doctors to ask for a prescription of Naloxone. By being able to get it over the counter at a chemist, it means

you are much more likely to obtain initial and refill packs in a timely manner

- Naloxone is a safe drug and has no effect on someone with no opioids in their system. You can't abuse it, it has no resale value, it is inexpensive to provide, fast acting and a reliable antidote for opioid overdoses.
- Naloxone is simple to administer by witnesses of an overdose, with limited instruction therefore all persons should be able to administer it with simple instruction from a pharmacist
- Having Naloxone in your bag is the same as someone with allergies having an epipen. It's a way to save lives, circumvent possible death, and then when ambulance staff arrive they are dealing with a person still living. Its vital for the health and wellbeing of people who use opiates!

Tasmanian Users Health and Support League (TUHSL)

Submission on Proposed Amendments to the Poisons Standard (Medicines)

Naloxone	To amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

The objectives of the Tasmanian Users Health and Support League (TUHSL) are to:

- provide support, education and advocacy, and to reduce further transmission of HIV/AIDS, hepatitis B and C and to reduce the harms and hazards (including overdose prevention and management) amongst Tasmanians associated with substance use; and
- reduce the stigma and discrimination associated with drug use and to be a credible and valued resource within the community ensuring optimum service delivery to its members.

The TUHSL welcomes the opportunity to provide the following submission in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

Suggested improvements
The TUHSL supports the amendment for the scheduling of naloxone and does not suggest any further improvements.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
The TUHSL supports the amendment for the scheduling of naloxone.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
The Tasmanian Users Health and Support League (TUHSL) is the Tasmanian drug user organisation, and the state member of the peak body Australian Illicit and Injecting Drug Users League (AIVL). Despite receiving no funding from State or Commonwealth Government, TUHSL continues to advocate on behalf of members. Based on the following points, we believe the amendment should go ahead: • Members of TUHSL continue to be at risk of opiate related overdose and access made easier through the rescheduling of naloxone would significantly decrease this risk; • Prompt use of naloxone is critical and there is often a significant time lapse between reporting an overdose and waiting for an ambulance with naloxone to arrive which increases the risk of fatality or brain damage. Response times can be shortened and lives can be saved; • There is often someone else present during an overdose and access would mean that family members or friends could administer naloxone if they had a supply on hand; • The wider distribution of naloxone has little risk of harm if administered to a person not experiencing an opioid overdose and is shown to have no risk of misuse because of its antagonistic properties and lack of psychoactive effect; • Naloxone is a safe drug and has no effect on someone with no opioids in their system. It cannot be abused, it has no resale value, it is inexpensive to provide, fast acting and a reliable antidote

for opioid overdoses;

- Experiences in other countries and in some Australian jurisdictions where naloxone has been widely distributed in the drug using community show that thousands of lives can be saved. Naloxone pilot programs in several Australian cities operating in partnership with government bodies, medical professionals and drug user organisations (not Tasmania), have demonstrated the effectiveness of targeting people who are most at risk of overdose, namely people who inject drugs. These community members are trained in overdose response (along with family and friends), to recognise and better manage opioid overdose through resuscitation techniques and the administration of naloxone to reverse the effects of an overdose (of which a kit is distributed as a component of the training);
- There is a fear for TUHSL members to access naloxone from their GP as they will have to disclose their drug use and fear corollary discrimination;
- In addition, there is a fear disclosure will jeopardise their continued prescription of opiate substitution therapy (methadone);
- Sometimes it can be hard to organise a GP appointment to ask for a prescription of naloxone. By being able to get it over the chemist counter, it means a person is much more likely to obtain the initial and refill packs in a timely manner;
- Naloxone is simple to administer by a witnesses of an overdose, with limited instruction therefore all persons should be able to administer it with simple instructions from a pharmacist;
- The scheduling amendment provides an opportunity for TUHSL members to enhance overdose education strategies to affected community members, families and friends.

The Tasmanian Users Health and Support League (TUHSL) supports the Proposed Amendment to the Poisons Standard (Medicines) for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

Alcohol, Tobacco & other Drugs Council Tas Inc.

Submission to the Australian Government
Department of Health
Therapeutic Goods Administration

Proposed Amendments to the Poisons Standard (Medicines): Naloxone

May 2015

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The Alcohol, Tobacco and other Drugs Council

The Alcohol, Tobacco and other Drugs Council of Tasmania (ATDC) is the peak body representing the interests of community sector organisations (CSOs) that provide services to people with substance misuse issues in Tasmania. The ATDC is a membership based, independent, not-for-profit and incorporated organisation.

The ATDC is the key body supporting the sector to secure adequate systemic support and funding for the delivery of evidence based alcohol, tobacco and other drug (ATOD) initiatives. We support the sector through training and sector capacity building, as well as undertaking policy and development projects with, and on behalf of, the sector.

We represent a broad range of service providers and individuals working in prevention, promotion, early intervention, treatment, case management, research and harm reduction.

We play a vital role in assisting the Tasmanian Government to achieve its aims of preventing and reducing harms associated with the use of alcohol, tobacco and other drugs in the Tasmanian community.

By working with all levels of government and the community the ATDC seeks to promote health and wellbeing of all Tasmanians through a reduction of the harms caused by substance use. Our priorities are set by the membership and Board and focus on the prevention of the uptake of harmful alcohol or drug use, the provision of effective treatment for alcohol or drug misuse and the long term promotion of health and relapse prevention.

A broad and regionally dispersed membership base ensures the ATDC maintains a strategically relevant position within the overall understanding of what services are provided, what services are needed and how best to achieve the goal of reducing the negative impacts on the Tasmanian community from alcohol and drug use.

Our Vision

A Tasmania without drug or alcohol related harm or discrimination.

Our Mission

To provide independent leadership and advocacy; strengthen partnerships through inclusion, and support consumer participation in the promotion of holistic alcohol, tobacco and other drug (ATOD) services for all Tasmanians.

Our Goals

Goal 1: To provide effective leadership and representation for the alcohol, tobacco and other drugs sector.

Goal 2: To build sustainability of the ATDC and the alcohol, tobacco and other drugs sector.

Goal 3: To maximise consumer engagement in service planning and delivery.

Introduction

The Alcohol, Tobacco and other Drugs Council welcomes the opportunity to provide a submission to the Australian Government on the proposed amendments to the current Poisons Standard.

In line with section 52E of the *Therapeutic Goods Act* 1989, this submission relates to amending the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

The ATDC looks forward to the release of the scheduling decisions after due consideration.

Suggested Improvements

The ATDC supports the amendment for the scheduling of naloxone and does not suggest any further improvements.

Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you

The ATDC supports the amendment for the scheduling of naloxone.

An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits

The jurisdictional report on Tasmanian drug trends for 2012 interviewed 106 people who regularly injected illicit drugs. One-quarter of the sample reported ever having experienced an opioid overdose and 6% reported this occurring in the preceding 12 months from use of methadone, morphine and oxycodone. The report noted:

- Two-thirds (64%) of the Tasmanian sample had used morphine that had not been prescribed to them in recent months;
- MS Contin remained the predominant preparation used by this group, used by 88% (of recent morphine users);
- Kapanol was reported as the next most commonly used (51%);
- Illicit oxycodone use among local injecting drug user samples has increased in recent years, from 30% reporting use in 2005 to 56% in 2012;
- OxyContin tablets were the predominant formulation used in the preceding six months;
- Illicit methadone syrup was used by 29% in the past six months, approximately once per week. Almost half of the respondents reporting recent use of illicit syrup (48%) were themselves enrolled in methadone maintenance treatment during this period;
- Illicit Physeptone varied between 37% and 52%, with no clear trend discernible. However, since 2009, the rate of recent use has decreased from 50% to 34% in 2012 which coincided with it being

regarded as 'difficult' or 'very difficult' to access and the median price of illicit Physeptone tablets had doubled between 2010 and 2011 from $10 to $20.

The number of accidental deaths in Tasmania attributable to opioid use in 2008 was 11, which equates to a rate of 2.2 per 100,000 persons. Nationally this compared to 500 deaths being attributed to such causes, which equates to a rate of 2.3 per 100,000 persons[1].

Alcohol, tobacco and other drug services, consumer organisations, people who inject drugs, their families and friends and medical associations have been calling for naloxone to be more widely available in the community.

Opioid overdoses are estimated to cause approximately one death per day in Australia. Other people (eg family members or friends) are often present at the time an overdose occurs and are eager to respond, and in the event of naloxone availability, would be in a position to administer naloxone. The opioid antagonist naloxone can quickly reverse the effects of opioid overdose. A substantial body of evidence shows that expanding naloxone availability, and training potential overdose witnesses to administer naloxone is a remarkably safe and effective intervention for preventing opioid overdose fatalities, with the potential to prevent opioid overdose related injury.

In most Australian States and Territories programs are in place to train potential overdose witnesses in overdose management and provide naloxone on prescription to people at risk of opioid overdose. Tasmania does not have such a trial and the amendment to scheduling would bring forward the development of such a program in this State. There is no evidence that expanding naloxone availability encourages riskier drug use or has any other adverse consequences.

In 2012, the Prime Minister's Alcohol and other Drug Advisory Body recommended:

- That naloxone be rescheduled to be made available as a pharmacist only medicine (S3) or as a pharmacy medicine (S2).[2]

The Australian Medical Association policy position also supports the availability and distribution of naloxone in a properly administered program.

Recommendation

The Alcohol, Tobacco and other Drugs Council of Tasmania supports the abovementioned recommendation and hence the Proposed Amendment to the Poisons Standard (Medicines) for the scheduling of naloxone.

[1] de Graaff, B., Bruno, R. (2013) *Tasmanian Drug Trends 2012: Findings from the Illicit Drug Reporting System (IDRS)*. University of Tasmania Hobart

[2] Australian National Council on Drugs (2012) *ANCD Position Statement: Expanding Naloxone Availability*. Canberra

CREIDU

Centre for Research Excellence into Injecting Drug Use

Submission to the TGA consultation on naloxone rescheduling

Authors

Submitted by Professor Paul Dietze and Amy Kirwan on behalf of the Centre for Research Excellence into Injecting Drug Use, CREIDU

The Centre for Research Excellence into Injecting Drug Use (CREIDU) is funded by the National Health and Medical Research Council to improve the health of people who inject drugs through research that generates new evidence and informs public health policy and practice. CREIDU brings together experts in injecting drug use from across Australia working in research, policy and practice. CREIDU wishes to make this submission on behalf of our members and key stakeholders.

CREIDU also auspices the Naloxone National Reference Group, a working group which include services and communities directly involved in the implementation of the 'take home naloxone' programs described below. CREIDU supports increasing the availability of naloxone in Australia to assist in reversing opioid overdoses which occur in the community.

The Therapeutic Goods Administration (TGA) is seeking submissions in relation to amending "the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3".

Our submission supports amending the scheduling of naloxone from Schedule 4 to Schedule 3.

1. Background

Opioid overdose is one of the key drug related harms in Australia. There were at least 613 accidental opioid-related deaths in 2010. (1) Responses are available, but they are limited in their effectiveness, meaning that new approaches are required to prevent opioid-related deaths (2).

Naloxone is a powerful opioid antagonist that has been used for the purposes of reversing the effects of opioids for over 40 years (3). In this capacity it has a variety of applications, but the most noteworthy is when it is used to reverse opioid overdoses. In Australia, this typically happens when ambulances are called to overdose events and naloxone is administered by paramedics. It is also used by emergency staff when needed in the Emergency Department (ED). Access to naloxone varies by jurisdiction in Australia but it is generally available for use by paramedics and medical practitioners for reversing the effects of opioids (4). Indeed, the drug has been available on prescription in Australia for many years, and was listed on the Pharmaceutical Benefits Scheme in April 2013. The naloxone that is now available in Australia on the Pharmaceutical Benefits Scheme is in the form of a pre-filled syringe, or Minijet®, manufactured by UCB Pharmaceuticals. Although this formulation requires a needle to be attached to the syringe prior to use, and is suitable for intramuscular administration, there is scope for other routes of administration, such as intranasal, where a needle may not be required in future (5). These Minijets are currently available only in 400 microgram doses, a relatively small dose by international standards, and larger doses than this are often used in reversing opioid overdoses (6).

Naloxone is a drug with no documented abuse potential and no health or life threatening consequences if misused deliberately or used inappropriately (7).

2. Responding to opioid overdose

Research shows that there is considerable scope to intervene at opioid overdoses: most occur a considerable time after the use of the drug, with others present who could intervene effectively if given appropriate education and training on how to respond (7). There is evidence that simple bystander responses can significantly improve outcomes for people experiencing overdose (8). Indeed, both mortality and morbidity can be improved with more timely opioid overdose response; opioid overdose deaths are largely avoidable (2, 3, 7).

3. Take Home naloxone

Programs have been established to make naloxone more widely available so that it can be administered by people other than medical professionals to reverse opioid overdose in community settings (3, 7, 9). Termed ‘take-home’ naloxone (THN) or ‘peer distribution of naloxone’, these programs have been established in many countries since the first published reports of programs in the mid 1990s (10). International program guidelines for THN have

now been issued by the World Health Organisation (7). Largely as a result of the Australian heroin 'drought' (11) Australia has been a late adopter, with this country's first THN program only commencing in 2012 in the ACT (12). This was soon followed by similar prescription naloxone programs in New South Wales. Programs have since been established in South Australia, Western Australia and Victoria, with a fledgling program started in Queensland. The basic principle of existing programs is to provide training to potential overdose witnesses and victims on how to prevent and best respond to overdose (typically including airway management, basic life support, calling an ambulance, naloxone administration, and monitoring the victim) and then provide naloxone, or at least a prescription for naloxone, at the end of the training (7, 9, 12). The training models vary, reflecting program variations seen overseas (13, 14), however the primary target group of most THN programs is people who inject drugs (PWID) who use opioids. As THN programs have evolved in Australia, studies of PWID show increased awareness of the programs (15).

Most Australian THN programs have been run by peer-based drug user representative organisations (e.g, Canberra Alliance for Harm Minimisation and Advocacy, Harm Reduction Victoria). To date, we estimate that around 1000 people have been provided THN through their participation in take-home naloxone programs. Importantly, a significant number of reversals have been reported by participants in these programs. For example, at least 60 reversals were reported to the Harm Reduction Victoria program (of 475 trained participants) though to April 2015 (http://hrvic.org.au/overdose/naloxone-update/).

4. Risk of overdose

The main target group for take-home naloxone programs has been PWID who use opioids. This is because most opioid related deaths in Australia involve current or past exposure to injecting. PWID are traditionally a disadvantaged population, with poorer health and wellbeing than the general population and poorer outcomes across a range of domains (16). As a consequence, many are in receipt of government benefits with limited capacity to pay for medicines.

Within the broader population of PWID, those most at risk of opioid overdose include marginalised groups such as recently released prisoners, people who use opioids in public settings and people who have overdosed previously (17-19). Furthermore, those at risk of opioid overdose may be reluctant to call ambulances in the case of an overdose for fear of negative repercussions such as police attendance (20). Resourcing these groups with access to life-saving measures, and associated education, assists in both encouraging them to seek emergency medical care from professionals but also to administer life support themselves.

5. Costs and target groups

It is likely that groups other than PWID are now also at risk, such as those presenting with non-cancer chronic pain (21-23). We understand that there will be no cost implications for

the key target group in rescheduling naloxone to Schedule 3. We note that the current cost of naloxone for people on Health Care Cards is low (around $6for up to five 400mcg Minijets), and that this cost structure would remain for people obtaining naloxone through the S3 scheduling (i.e. over-the-counter) with a health care card. Cost implications should be a key consideration in any rescheduling, with the potential to even reduce costs for those not on a Health Care Card a possibility that should be factored into the TGA decision.

6. Barriers to THN programs

Most THN programs in Australia have received only limited funding for their activities, which has impacted on the scope and reach of existing programs, despite the potentially life-saving initiative being relatively low cost. Any initiative that has the potential to reduce costs to consumers and program providers and increase the accessibility and availability of naloxone is strongly supported by CREIDU.

7. Clear benefits of re-scheduling

Any strategy which lowers the threshold for disadvantaged and marginalised at risk individuals to access naloxone will be beneficial. Italy has had naloxone available over-the-counter since 1985, with no reported adverse effects. We believe that this shift would be of significant benefit here in Australia. Although there has been considerable success in reaching PWID, the key risk group in Australia, there is an urgent need for scale-up to reach more PWID, particularly those most at risk of overdose such as recently released prisoners (18), and people in other risk groups such as prescription opioid users (21). The ability to access naloxone under an S3 schedule will be an important step in this direction as it may provide extra opportunity for the engagement of pharmacists in the wider distribution of naloxone, particularly those engaged in dispensing as part of opioid substitution therapy (OST). Importantly, it will provide a simple mechanism for individuals who have participated in THN programs to replenish supply after they have used their supply or their supply is unavailable for other reasons (e.g. past expiry date).

8. Additional considerations

Pharmacists and representative bodies will need to develop mechanisms for training and quality assurance to ensure that those who obtain naloxone have the requisite skills to recognise the circumstances when the drug should be administered and subsequently how to administer the drug. Further, consideration will need to be given to appropriate packaging given that the Minijet® does not come with a needle supplied. Finally, work will need to be undertaken to raise awareness of the accessibility of naloxone amongst the target groups and pharmacists given the likelihood that individuals will obtain naloxone for use in emergency situations.

9. References

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Proposed amendment to the scheduling of naloxone

Ballarat Community Health is an organisation committed to promoting the health and wellbeing of our most disadvantaged communities. We are lead agency for the Grampians Alcohol and Drugs Consortium of treatment service providers and offer a range of alcohol and drug treatment programs for adults and youth; we also operate a needle and syringe program from all of our sites. We are the lead agency for ORTicare Pharmacotherapy Network. ORTicare is a clinical network of health professionals dedicated to promoting opioid replacement therapy across the Grampians and Loddon Mallee Regions of Victoria.

Ballarat Community Health is already actively involved in the promotion of 'take home naloxone' for those in our community who are at risk of opioid overdose. We would welcome the re-scheduling of this life-saving and low risk drug to be made available over-the-counter, as the current prescription-only availability is a significant barrier to access. Overdose from both legal and illegal drugs is a significant concern for rural and regional areas including the communities we serve, and opioid analgesics play an increasing role:

- In 2012-13 the rate of ambulance attendances for opioid analgesic use was significantly higher in regional Victoria than in metropolitan Melbourne, at a rate of 242 per 1 million population (compared with 169 in Melbourne) [1]

- Horsham was the Victorian regional LGA with the highest rate, at 61 ambulance attendances per 100,000 of population. Northern Grampians Shire was the fourth highest in regional Victoria at 42 attendances per 100,000[2]

- Also in 2012-13, Ballarat was the second highest regional LGA in Victoria for heroin-related ambulance attendances, with 15 attendances throughout the year. Seven of these involved the administration of naloxone.[3]

- In 2012, the accidental fatal overdose rate in regional Victoria was 3.19 per 100,000 people, surpassing that of Melbourne at 3.01. This is partly attributed to a rise in use of prescription opioids such as oxycodone and fentanyl.[4]

Our increasing concerns around analgesics and fatal overdose reflect trends seen across Australia. Nationally, accidental overdose deaths among women aged 30 to 50 are at their highest since the turn of the century. However, these deaths are now more likely to be related to use of prescription painkillers than to involve heroin, as was the case fourteen years ago. More than four times as many women in this age group are dying from accidental overdose than in a car accident.[5]

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[1] Lloyd B, Matthews S, Gao C: "Trends in alcohol and drug related ambulance attendances in Victoria 2012/13", Turning Point/Ambulance Victoria, May 2014, p.1.
[2] Lloyd, Matthews, Gao, pp. 138 - 140
[3] Lloyd, Matthews, Gao, pp. 82 – 91.
[4] Penington Institute: "Overdose deaths higher in regional and rural areas than capital cities for first time," Web, 26th August 2014.
[5] Penington Institute: "Female accidental overdose deaths near 'heroin glut' era", Web, 13th August 2014.

We are aware of the World Health Organisation guidelines and recommendations released in November 2014, which support greater community access to naloxone for overdose reversal along with appropriate training. We have been working in partnership with the Penington Institute and Harm Reduction Victoria to access training for support staff, clients and their family members or other likely 'bystanders'. However, the scheduling of naloxone as a prescription-only drug remains an ongoing barrier to uptake for our clients. Clients of our needle syringe program who are reluctant to approach a doctor for naloxone cite the following reasons:

- Discomfort around disclosing their drug use to their family doctor
- Working full-time and having little opportunity for the long waiting times often involved in seeing a doctor
- Negative past experiences with judgmental doctors.

From the perspective of the doctors we work with, prescribing naloxone can be an additional time burden when working with patients who are often presenting with multiple and chronic conditions requiring a treatment response. Doctors also raise potential medico-legal concerns around prescribing a drug to their patient that may be administered to a third party – although the risks associated with naloxone are extremely low and the abuse potential non-existent, this concern is a barrier for some professionals. The time and resources required to educate health professionals in order to shift attitudes around prescribing naloxone is significant, especially when compared to the potential ease and benefit of having it available over the counter. Pharmacists are very well-placed to provide expert advice and guidance to consumers and already do this on a daily basis for drugs with a much higher risk and abuse potential.

As an organisation wholly committed to harm reduction, we most certainly support any move to make take-home naloxone more readily available. We will continue to advocate for its uptake and provide training and support to our clients, staff and community around emergency responses to overdose. The re-scheduling of naloxone to Schedule 3 would greatly enhance the potential for this drug to reach many more people at risk of opioid overdose.

This submission has been endorsed by

[redacted]

[redacted]

For any further information regarding this submission please contact

[redacted]

ATODA
Alcohol Tobacco & Other Drug Association ACT

Submission to the public consultation on the proposed amendments to the Poisons Standard (Medicines)

Thank you for the opportunity to present a submission to the Advisory Committee on Medicines Scheduling (ACMS) as part of the current TGA public consultation on the proposed amendments to the Poisons Standard (Medicines).

This is a matter of considerable interest to the Alcohol Tobacco and Other Drug Association ACT (ATODA) as having naloxone more readily available, in the Canberra and the Australian community, has considerable potential for producing good health and social outcomes.

About the Alcohol Tobacco and Other Drug Association ACT

ATODA's vision is a community with the lowest possible levels of alcohol, tobacco and other drug (ATOD) related harm, as a result of the ATOD and related sectors evidence-informed prevention, treatment and harm reduction policies and services.

ATODA works collaboratively to provide expertise and leadership in the areas of social policy, sector and workforce development, research, coordination, partnerships, communication, education, information and resources. ATODA is an evidence informed organisation.

The ways we work, and the outcomes we strive to achieve, reflect our commitment to the values of population health, human rights, social justice and reconciliation between Aboriginal and Torres Strait Islander people and other Australians.

The mission of ATODA is to be the peak body representing and supporting the ATOD sector and community in the ACT.

The proposal

ATODA understands that the ACMS is seeking submissions specifically addressing the proposal 'To amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3'.

The ACT naloxone experience

The research evidence indicates that providing naloxone, with appropriate training, to opioid users and to potential overdose witnesses such as their family and friends, can result in successful overdose reversal in a safe and effective way. For example, a US comparative study indicated that providing naloxone hydrochloride and training

to drug users, their families and friends involved a reported 10,171 overdose reversals.[1]

In December 2011, Australia's first overdose management program was launched in the ACT, providing naloxone on prescription to potential overdose victims. Independent evaluators released an interim findings report on 13 February 2014, assessing the implementation fidelity and participants' experience of the program.[2]

The findings revealed that the 140 program participants evaluated displayed a higher knowledge of overdose identification and response after the completion of the training compared to before.

The report also revealed that they were able to administer naloxone in a non-medical setting which resulted in 23 successfully reported overdose reversals. The evaluation concluded that the ACT take-home naloxone program was overwhelmingly positive.

Supporting other submissions

- We refer the ACMS to the Pennington Institute's submission summarising the evidence and efficacy of naloxone
- We also refer the ACMS, and lend our support, to the submission made by the Public Health Association of Australia

Please don't hesitate to contact us if we can provide further information or support.

Thank you for your consideration and support promoting the health of people who are at risk of opioid overdose and their families and friends.

Alcohol Tobacco and Other Drug Association ACT (ATODA)
[redacted]
info@atoda.org.au
www.atoda.org.au

7 May 2015

[1] Wheeler E, Davidson, PJ, Jones, TS and Irwin, KS. Community-Based Opioid Overdose Prevention Programs Providing Naloxone (2012) *MMWR. Morbidity and Mortality Weekly Report*, *61*(6), 101–105.
[2] Key Interim Findings – Independent evaluation of the 'Implementing Expanding Naloxone Availability in the ACT (I-ENAACT)' Program, 2011-2013 - http://www.atoda.org.au/wp-content/uploads/Summary-of-Interim-Findings-summary-for-release-2.pdf

UnitingCare ReGen support for proposed rescheduling of naloxone

Summary position

UnitingCare ReGen supports the proposed rescheduling of naloxone to increase its accessibility for people likely to be the first responders to potentially fatal overdoses. Including naloxone in Schedule 3 will allow pharmacists who dispense opioids (including opioid replacement therapies) to co-dispense the drug. This is an ideal service context to increase the accessibility of naloxone to people at immediate risk of overdose and ensure that education about naloxone can occur at the point of dispensing.

As with use of Epipens in the case of anaphylaxis, peers, family members and non-medical workers are safely able to administer intramuscular naloxone, when provided with basic training.

The work of Harm Reduction Victoria (having trained over 450 people in naloxone administration since 2013, resulting in 60 reported overdose reversals) is an indicator of the potential scale of impact that increased availability could have for Australian families and the broader community.

Increasing the accessibility of naloxone to peers, family members and a wide range of service providers will save lives, support more effective treatment services and prevent the widereaching trauma associated with opioid overdoses in Australia.

Scope and purpose of submission

The following comprises UnitingCare ReGen's response to the Invitation for public comment - Advisory Committee on Medicines Scheduling meeting, July 2015. The comments included in this submission relate to the following proposed amendment:

- 'To amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3'

Background on UnitingCare ReGen

UnitingCare ReGen has 45 years' experience delivering a comprehensive range of alcohol and other drug (AOD) services to the community. It is one of the largest providers of AOD treatment and education services in Victoria and a critical contributor to the ongoing development of evidence-based policy and practice.

ReGen's comprehensive range of services for individuals and families enables us to provide effective early education or treatment interventions where people are at risk of, or

experiencing, early stage AOD-related harms. We also provide more intensive services for adults or young people who require greater levels of support or medical care.

In recognition of the importance of building on current naloxone initiatives in Victoria and the recent rise in opioid-related presentations to its services, ReGen is currently establishing a self-funded Opioid Intoxication and Overdose Response project to support the implementation of the Victorian COPE project (see below) and increase the capacity of ReGen employees, consumers and family members to:

- Recognise the signs and symptoms of overdose, and discriminate between overdoses on different types of drugs;
- Safely administer naloxone; &
- Successfully resuscitate people who are experiencing opioid overdose.

Comments

Nearly four Australians die every day from overdose.

Deaths from opioid overdose are not instantaneous. Overdose most commonly occurs in private residences and are frequently witnessed by peers or family members. An immediate response to an identified overdose has the greatest likelihood of preventing death and potential injury (due to prolonged reduction in oxygenation of the brain, muscles or other organs) resulting from non-fatal overdoses. The impacts of such injuries (particularly brain injuries) have long term impacts on people's wellbeing and the capacity of community services and the Australian health system.

There is well established research evidence demonstrating the link between delays in overdose response and subsequent fatalities or permanent injuries. Delays can be caused by witnesses' fear of police involvement when calling paramedics, lack of knowledge in identifying and responding to overdose and lack of access to naloxone.

There is a clear benefit in providing people who are likely to witness an opioid overdose with naloxone.

Peer administered naloxone programs have been operating internationally since 1995. While there is not yet a base of peer reviewed, random controlled trials to confirm their effectiveness, program evaluations have consistently demonstrated their impact on reducing the risk of overdose fatalities and empowering families/peers to save lives (Dietze & Lenton, 2012). Naloxone is increasingly being carried by police, paramedics and other 'first response' services in the USA and other countries.

The first Australian trial program commenced in the ACT in 2012. In Sydney, the Kirketon Rd & Langton Centres have been running low-key naloxone programs. Sydney's Medically Supervised Injecting Centre also runs a naloxone 'take-home' program and is currently undertaking a research trial comparing the effectiveness of intramuscular and intranasal delivery.

Since the commencement of naloxone programs in Australia, there have been repeated calls to shift the perception of naloxone programs as 'trials' towards their recognition as core business for the AOD sector.

There have been positive recent developments to increase the accessibility of naloxone in Victoria. The State Government funded COPE project (implemented by the Penington Institute) to provide training and support to primary health and community organisation staff. Since commencing their self-funded naloxone peer training in 2013, Harm Reduction Victoria have trained over 450 people in the use of the drug. In that time, the organisation has reports of 60 overdose reversals performed by training participants.

This tremendous outcome is one that could be replicated across Australian communities if the accessibility of naloxone is increased. Increasing the capacity of peers, partners and family members to reverse opioid overdoses and save lives will bring at least two clear benefits:

1. Keeping individuals alive to allow opportunities for them to participate in treatment services and recovery supports, rebuild their lives and contribute to their communities; &
2. Reducing family members' stress (and potential trauma) at being unable to reverse a loved one's opioid overdose.

Increasing the accessibility of naloxone to individuals, families and a wide range of service providers will save lives, support more effective treatment services and prevent the widereaching trauma associated with opioid overdoses in Australia.

The proposed amendment to naloxone's scheduling will be a key enabler of future initiatives to prevent opioid overdose, reduce the harms associated with the use of opioids within our communities and support improved treatment and recovery outcomes.

TGA Consultation on Naloxone

The TGA are considering a request to reschedule Naloxone to an 'over the counter' medication. They are accepting submissions (people's views) on this until COB Thursday 7th May

The request:

Naloxone	To amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

Address: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone and do not suggest any further improvements
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
Questions to possibly answer I have been present at an overdose incident and I think it would have been an easier process to manager if we had had Naloxone readily available.

General statements you could use

The people I know and love are at risk of Overdose and I don't want them to die. Easy access to naloxone will significantly decrease this risk.
Prompt use of naloxone is critical and there is often a significant time lapse between reporting an overdose and waiting for an ambulance with naloxone to arrive which increases the risk of fatality or brain damage. Response times can be shortened and lives can be saved.

To whom it may concern,

My name is [redacted]. I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

I support the amendment with no changes.

I am connected with people who use opiates both professionally and personally. While I have not personally been present at an overdose, I am close to several people who have experienced overdose and have survived because of the use of Naloxone.

I believe that training and encouraging people who use drugs to carry Naloxone will be much more effective if Naloxone is available over the counter.

I believe that making Naloxone available over the counter will significantly improve access in regional and rural areas, as well as in communities (like some Aboriginal communities) where access to health care is limited.

Naloxone is extremely time sensitive: it is very important to use it quickly in event of an overdose. This means that more lives will be saved if Naloxone is easy and common for opiate users to carry with them.

Additionally, I have recently been prescribed [redacted], but am still unfamiliar with them. As I take a number of other prescription medications, I would feel comfortable having Naloxone in the house in case of an accidental overdose. However, I am unlikely to seek out a prescription for Naloxone as I fear my doctor would consider me “drug seeking” or attach stigma associated with recreational drug users to me.

Thank you for your time.

Regards,

[redacted]

Advisory Committee for Medicines Scheduling

Therapeutic Goods Administration

c/- medicines.scheduling@tga.gov.au

To whom it may concern

ADVISORY COMMITTEE FOR MEDICINES SCHEDULING MEETING JULY 2015

I am writing on behalf of Hepatitis NSW in regards to the upcoming July 2015 meeting of the Advisory Committee for Medicines Scheduling.

Hepatitis NSW is an independent, community-based, non-government health promotion charity funded by the NSW Ministry of Health. We provide information, support, referral and advocacy for people affected by viral hepatitis in NSW. We also provide workforce development and education services both to prevent the transmission of viral hepatitis and to improve services for those affected by it.

We strive to be representative of people affected by viral hepatitis and work actively in partnership with other organisations and with the affected communities themselves to bring about improvements in quality of life, information, support and treatment, and to prevent transmission of viral hepatitis.

In terms of the July 2015 meeting of the Committee, Hepatitis NSW would like to endorse the submission made by the NSW Users & AIDS Association (NUAA) in support of amending the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 microgram/mL of naloxone or less in Schedule 3.

In particular, we acknowledge the real-world benefits of naloxone availability, including its vital life-saving capacity, which are highlighted in the NUAA submission, and strongly agree with NUAA these benefits will only increase if there is greater accessibility and availability of naloxone in the future.

If you have any questions about this letter of support, please contact our Policy & Engagement Manager, Mr Alastair Lawrie, on 02 9332 1853 or via alawrie@hep.org.au

Sincerely

[redacted]

[redacted]

[redacted]

Thursday 7 May 2015

Quality Improvement Council
'Yes ... we are a QIC accredited organisation'

Hepatitis NSW
working towards a world free of viral hepatitis

Hepatitis NSW *Hepatitis Infoline* 1800 803 990 www.hep.org.au
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PO Box 432 Darlinghurst NSW 1300 | Level 4, 414 Elizabeth Street, Surry Hills NSW 2010

BUILDING OUR COMMUNITY'S HEALTH & WELLBEING

7 May 2014

The Secretary
Advisory Committee on Medicines Scheduling
TGA
PO Box 100
Woden ACT 2606
(via email: medicines.scheduling@tga.gov.au)

To whom it may concern

Re: Public consultation on the proposed amendments to the Poisons Standard (Medicines)

We are writing to you in support of the proposal to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3 of the Poisons Standard (Medicines).

ACON is New South Wales' leading health promotion organisation specialising in HIV and lesbian, [redacted](LGBTI) health. Incorporated in 1985 as the AIDS Council of [redacted] as an innovative, successful organisation which has adapted to changes in the HIV epidemic and responded early to emerging health issues among our [redacted]. We run HIV prevention programs for the groups most at risk of HIV transmission [redacted]nject drugs. We run the two of the largest secondary outlet needle and syringe programs in NSW, distributing over 500,000 units of injecting equipment per year across all of our sites.

Naloxone is a safe drug that can save lives and reduce morbidity in people who experience opioid overdose. It is an important opioid antagonist that temporarily reverses the central nervous and respiratory systems effect during an overdose. It is not known to have any intoxicating or dependence forming effect, and therefore there is little chance for abuse of this drug. This negates the interest in misusing Naloxone to those who already use opioids.

The current scheduling arrangement has limited the potential of this life saving drug. The proposed scheduling is similar to other jurisdictions and one that we wish to see implemented in Australia. There have been successful trials of take home naloxone in Australia, including in the ACT, and they have been shown to be successful. Broadening access to more people who already use opioids as well as their peers, families and carers, and health and community services will open up the potential to prevent overdose morbidity and mortality that naloxone provides.

Price is still an important consideration for many people who would benefit from the use of naloxone. As such we support the call from the Pennington Institute, contained in their submission to your Committee, to maintain the current listing on the Pharmaceutical Benefits Scheme.

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ACON acknowledges the support of its primary funder, NSW Health

BUILDING OUR COMMUNITY'S HEALTH & WELLBEING

The change to the scheduling of Naloxone will need to be supported by education programs and resources. We believe that peer based organisations are best placed to support its proper use by developing education messages for the target group. We support the Australian Injecting and Illicit Drug Users League (AIVL) nationally, and in NSW their affiliate the NSW Users and AIDS Association (NUAA), in being funded to undertake these activities and would work with them to support efforts in reaching target communities once naloxone appears on Schedule 3.

ACON urges the ACMS to recommend the amendment to the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3 of the Poisons Standard (Medicines). ACON believes this change will benefit opioid drug users and help further minimise the harm caused by opioid overdose in Australia.

Should you require any further information please contact me on 02 9206 2122 or at nparkhill@acon.org.au.

Kind regards

[redacted]

[redacted]

[redacted]

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Hunter • Southern NSW • Mid North Coast • Northern Rivers
ABN 38 136 883 915 • Authority to Fundraise CFN/21473

ACON acknowledges the support of its primary funder, NSW Health

From: [redacted]
Sent: Thursday, 7 May 2015 3:28 PM
To: Medicines Scheduling
Subject: 'Proposed Amendments to the Poisons Standard (Medicines)

My name is [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

I support the amendment for the scheduling of naloxone and do not suggest any further improvements

I support the amendment for the scheduling of naloxone

If I were able to get Naloxone over the counter, I would definitely advertise the fact to family and friends and recommend people keep some handy just in case they witness an overdose.

I believe this would be particularly useful to those people that live in rural or remote areas and don't always have access to immediate emergency care when needed.

People I have known and loved are or have been at risk of overdoes – I can't imagine why something like naloxone shouldn't be easily and readily available to them, their family and their friends.

Regards,

[redacted]

[redacted]

Advisory Committee for Medicines Scheduling Meeting July 2015

Response by the Canberra Alliance for Harm Minimisation and Advocacy (CAHMA) to the invitation for public submissions on the application to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Contact:

[redacted]

CONTENTS

PART 1-SUMMARY OF SUBMISSION

1.1 PROPOSED SCHEDULING/RESCHEDULING TO THE POISONS STANDARD

CAHMA refers to the invitation for public comment on the application made to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

CAHMA agrees with the proposed rescheduling and provides this submission in support of the existing rescheduling application. The only proviso is that this amendment does not affect the current capacity to access naloxone under existing Schedule 4 provisions.

1.2 SUGGESTED SCHEDULING

(a) **Schedule 3 – proposed new entry**

NALOXONE in single-use preparations for prefilled injection containing 400 micrograms/mL of naloxone or less.

(b) **Schedule 4 – modified entry**

NALOXONE **except** when included in Schedule 3.

PART 2-BODY OF SUBMISSION

2.1 NALOXONE AND ITS CURRENT USES

Naloxone hydrochloride, also referred to simply as naloxone or by its street and brand name Narcan®, is an "opioid antagonist". Naloxone temporarily reverses the life-threatening depression of the central nervous and respiratory systems that occurs in overdose of opioid drugs. It is currently listed as a Schedule 4 Prescription Only Medicine. Naloxone is not habit forming. There is no other use than as a way to reverse the effects of opioids. It has no other use and possesses no 'black market' value. .

Since the 1970s naloxone has been used by paramedics and in hospital emergency departments to reverse the effects of opioids where people were at risk of suffering a life threatening overdose. Thousands of lives have been saved through utilising naloxone in such circumstances.

Naloxone, as a Schedule 4 medicine, may be safely and legally administered by a lay person, but only to the person named in the prescription. The current scheduling limits the potential for more fatal overdoses to be averted. If there is a provision for the single use injection form of naloxone to be available as an S3 drug the limitation that the drug be only used for named persons is removed. There are circumstances, for example in drug treatment facilities, where the identity of a specific overdose victim may not be known before the event. In these cases naloxone could be legally used by a lay person if it had been obtained as a Schedule 3 drug. In this circumstance, the control point would be with the pharmacist who would be in a position to assess whether the intended use was safe and appropriate.

At present, naloxone is only available to people at risk of overdose, through a prescription. While it is encouraging that there are now some take-home naloxone programs in Australia, the coverage and scale of these programs is limited. There is a need to increase access to this lifesaving drug, as is occurring in a number of nations such as the United States.

It is clear that naloxone is not currently being used to its full potential as an opioid antagonist in overdose situations. Scheduling the single-use pre-filled syringe 400µg/1mL as a Pharmacist Only medication, while maintaining it on the PBS, will increase the options available to community members wishing to receive naloxone.

Rescheduling single use naloxone to Schedule 3 of the *Poisons Standard* would greatly reduce barriers to access for the drug.

2.2 THERAPEUTIC GOODS ACT 1989 - SECT 52E

Secretary to take certain matters into account in exercising powers.

Clearly S 52 E of the Therapeutic Goods Act (1989) is critical to weighing up various factors before making any decision to alter scheduling;

(a) the risks and benefits of the use of a substance;

(b) the purposes for which a substance is to be used and the extent of use

(c) the toxicity of a substance;

(d) the dosage, formulation, labelling, packaging and presentation

(e) the potential for abuse of a substance;

(f) any other matters that the Secretary considers necessary to protect public health.

The pharmacology of naloxone presents no significant issues under S 52E. In fact, CAHMA strongly supports any initiative that enhances access to naloxone for any user of opioids whether licit or illicit.

PART 3-CAHMA INTEREST IN THIS ISSUE

CAHMA has a clear interest in any proposals to change the scheduling of naloxone. As the peer-based drug user organisation in the ACT we exist to advocate for and promote the health and human rights of people who use, or have used, illicit drugs. Educating opioid users to protect themselves against overdose has always been a priority for CAHMA.

CAHMA put in the submission and developed the recognition of opioid overdose and response training materials that led to the first ever naloxone program in Australia being funded by the ACT government. The Implementing Expanding Naloxone Availability in the ACT Committee (I-ENAACT) provided expert guidance and support to the CAHMA naloxone program. The program commenced on the 10th April 2012 and training sessions were run at a variety of sites in the ACT. CAHMA successfully completed the training of 200 current opioid users, including soon to be released detainees from the Canberra jail, the AMC. Some other jurisdictions have subsequently followed the lead established by CAHMA and established naloxone programs. These programs have successfully operated under the existing scheduling regime.

The experience of the CAHMA naloxone program has validated the urgent need for naloxone to be widely available to opioid users both licit and illicit. The benefit of expanding access by having a naloxone product accessible under Schedule 3 would be to enhance the likelihood of licit opioid users being given the protection of naloxone in the advent of an accidental overdose of their opioid medication(s). Naloxone has been available over-the-counter for decades in Italy.

The evaluation of the CAHMA naloxone program is due for publication and no serious concerns about the use or efficacy of naloxone have been found.

Overdose from the use of opioids, is a leading cause of accidental death in Australia. The administration of naloxone is able to prevent overdose fatalities. Naloxone is a safe drug to take, which only has effect when there are opioids present in the body. Consequently, it poses no potential for abuse. Naloxone is simple to administer and people can be confident to administer it after being trained.

At present, naloxone is only available to people at risk of overdose from using illicit opioids who are given a prescription. The success of the CAHMA naloxone program and other similar programs has proven the efficacy of naloxone to prevent overdose after using illicit opioids. There is an urgent need to increase access to this lifesaving drug, as is occurring in a number of nations such as the United States.

It is clear that naloxone is not currently being used to its full potential as an opioid antagonist in overdose situations. For all of the above reasons we believe that scheduling the single-use pre-filled syringe 400µg/1mL as a Pharmacist Only medication under Schedule 3, **while maintaining it on the PBS,** will reduce barriers and significantly increase the options available to members of the community wishing to receive naloxone.

<u>Unintended consequences</u>

While CAHMA supports scheduling of naloxone single-use preparations for prefilled injection containing 400 micrograms/mL to Schedule 3 for over the counter chemist purchase, we would ask that it retain dual-listing to allow it to be prescribed to Health Care card holders at a PBS subsidy. We would not support rescheduling if the most marginalised people in society – including many people at risk of opioid overdose – were effectively priced out of the market by removing it from the PBS. **This would undoubtedly cause deaths.**

CAHMA provide 5 minijets of 400 micrograms/ml to our trainees and consider this to be an optimal amount to ensure that any opioid overdose can be reversed. This will cost approximately $130 AUD across the counter once chemist costs have been included and this is out of reach for nearly every injecting drug user we have trained. As a tiny peer-based organisation CAHMA simply could not continue to train the numbers of people we have and also purchase naloxone at this level. Whereas we can currently offer, through a prescriber, PBS access and most of our clients are able to currently pay $6.10 for five minijets.

Nor are these one-off costs. A high proportion of trainees have requested renewed prescriptions for naloxone, and we do not wish to put up any further barriers, such as cost.

Thank you for the opportunity to comment.

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the proposed amendment for the scheduling of naloxone as stated & without improvements.
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
I support the amendment for the scheduling of naloxone.
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
As the [redacted] at the [redacted] I have been involved in the management of numerous overdoses requiring Naloxone during the seven years I have been in post. I am fully aware of the benefits of Naloxone, as not only does it prevent death caused by overdose, it also prevents catastrophic injuries caused by overdose, such as irreversible brain damage. The clients at the Sydney MSIC are able to access take-home Naloxone following a brief training session and a prescription from our Medical Director. When the Medical Director is on-site, clients can be dispensed Naloxone then and there. However when the Medical Director is not on-site, clients have to attend a local pharmacy where they are dispensed the Naloxone with a prescription. Due to the chaotic nature of many of our clients, this process is not always seamless, and they potentially lose out on the opportunity to be provided with a medication that will save someone's life. There is often someone else present during a drug overdose – wider availability of naloxone would enable these users to act promptly if an overdose occurs. Naloxone is a safe drug and has no effect on anyone without opioids in their system. You can't abuse it, it has no resale value, it is inexpensive to provide, fast acting and a reliable antidote for opioid overdoses. Naloxone is simple to administer by witnesses of an overdose, with limited instruction therefore all persons should be able to administer it with simple instruction from a pharmacist along with the reminder of written directions provided with packs of Naloxone . Having been involved in the delivery of "Opioid Overdose Identification & Management' training to services in the local community I am aware of the impact that wider availability of Naloxone would

have, and feel that this would increase the potential to save lives and prevent injury caused by overdose.

Advisory Committee for Medicines Scheduling
Meeting July 2015

Response by WA AIDS Council to invitation for public submission on application to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Closing date for submission – 7 May 2015

Contact person
Position
Contact details

[redacted]

Submission to Therapeutic Goods Administration Regarding Rescheduling of Naloxone

To amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

Summary of Submission

The WA AIDS Council supports the rescheduling of naloxone single use syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

The benefits of rescheduling in the manner proposed would be substantial. These would include widening the availability of naloxone for opioid users, thereby allowing services that work with opioid users to access naloxone and respond to opioid overdose, and the removal of barriers for medical practitioners who may be unwilling to prescribe naloxone due to concerns about naloxone being administered to a person other than whom it was prescribed to. This would enhance the ability to prevent and reduce opioid overdose morbidity and mortality, which is an issue of growing concern in Australia.

The risks of rescheduling naloxone are negligible, as naloxone has no other purpose than to reverse the life threatening respiratory depression associated with an opioid overdose. Naloxone has a high safety profile, with the only contraindication being an allergy to naloxone. It has no psychoactive effects, is short acting and essentially has no effects if used on a person who has not ingested opioids.

Naloxone availability to opioid users is a key strategy of opioid overdose prevention and management in Western Australia, along with other jurisdictions. It has been proven to be an effective strategy in reducing opioid-related fatalities in conjunction with airway management.

While the WA AIDS Council supports the application to change the scheduling of naloxone to a Schedule 3 drug, The Council echoes the issues raised by other submissions, including

- the need to ensure that naloxone remains on the Pharmaceutical Benefits Scheme in order to avoid increased costs to the consumer;
- the development of consumer product and administration information;

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- the importance of adequate training to identify and respond to opioid overdose including airway management and calling an ambulance; and
- consideration of similar scheduling for naloxone for intranasal administration.

Please find attached the response by Penington Institute to this invitation for public submission on application to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3. **WA AIDS Council support this submission and endorses it in its entirety.**

Western Australian AIDS COUNCIL Inc. ABN 66 376801 057
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Advisory Committee for Medicines Scheduling
Meeting July 2015

Response by Penington Institute to invitation for public submission on application to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Closing date for submission – 7 May 2015

CONTENTS

1. PART 1 – SUMMARY OF SUBMISSION

1.1 PROPOSED SCHEDULING / RESCHEDULING TO THE *POISONS STANDARD*

Penington Institute refers to the invitation for public comment on the application made to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Penington Institute agrees with the proposed rescheduling submitted for public consultation by July 2015, and provides this submission in support of the existing rescheduling application. To ensure that adequate detail has been included in this submission, Penington Institute has used the structure, and fulfilled the requirements of, a rescheduling application.

1.2 SUGGESTED SCHEDULING OR OTHER WORDING

(a) **Schedule 3 – proposed new entry**

NALOXONE in single-use preparations for prefilled injection containing 400 micrograms/mL of naloxone or less.

(b) **Schedule 4 – modified entry**

NALOXONE **except** when included in Schedule 3.

1.3 SUBSTANCE SUMMARY

Naloxone hydrochloride (also referred to simply as 'naloxone', and known by the brand name Narcan®) is a type of medication called an "opioid antagonist". Naloxone (CAS Number 465-65-6) is a life-saving medicine that temporarily reverses the life-threatening depression of the central nervous and respiratory systems that occurs in overdose.

1.4 OVERVIEW

Naloxone hydrochloride is an opioid antagonist that completely or partially reverses the effects of natural and synthetic opioids such as codeine, heroin, methadone, morphine and oxycodone. It is non-addictive and safe, primarily because it does little else but counter the depressant effects of opiates. Since the 1970s it has been used by paramedics and emergency room physicians to reverse the effects of opioids, including in people suffering a life threatening overdose. Thousands of lives are saved and severe brain injuries avoided each year by Australian paramedics who carry it with them as part of standard practice.

As in other parts of the world, there are now some small-scale programs in Australia where potential overdose witnesses (such as opioid injectors) are provided access to naloxone through what are known, in some areas, as 'take home naloxone' programs. These programs are conducted, for example, through health services and patients/clients receive a script which can then be claimed against the PBS. Although Australian trials are quite limited in scope, they have proved successful.

A limited rescheduling of naloxone from a Schedule 4 Prescription Only Medicine to a Schedule 3 Pharmacist Only Medicine would assist in providing much needed access to naloxone in the wider community. Pharmacists are highly educated medication specialists who are easily accessible to the public. A rescheduling would allow pharmacists to make several interventions that would improve many lives and reduce the number of fatal opioid overdoses in Australia.

2. PART 2 – BODY OF SUBMISSION

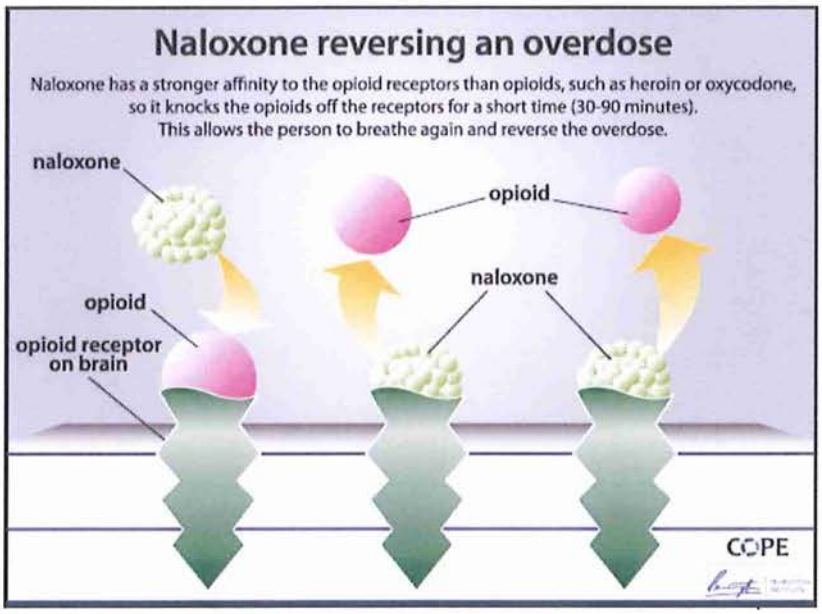
2.1 BACKGROUND

Opioids (such as oxycodone, morphine, heroin, codeine and methadone) are central nervous system depressants, which, in the case of overdose, gradually suppress respiration. Without intervention, opioid overdose can lead to permanent brain injury or death.[1]

Australia is in the midst of a prolonged and growing problem of accidental and preventable deaths associated with overdose of licit and illicit opioids.

Naloxone hydrochloride is an opioid antagonist. It works by knocking the opioids off the body's receptors for a short time (around 30 to 90 minutes), as indicated in the diagram below. This is because naloxone has a stronger affinity to the opioid receptors than many opioids.[2]

In Australia, naloxone is currently listed as a Schedule 4 Prescription Only Medicine.



Source: Adapted diagram from *Guide To Developing and Managing Overdose Prevention and Take-Home Naloxone Projects* http://harmreduction.org/our-work/overdose-prevention/

Figure 1: *The operation of naloxone*

CRITERIA TO BE SATISFIED FOR APPLICATION FOR RESCHEDULING (CHANGE TO PART 4 OF THE *POISONS STANDARD*)

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[1] Anex, Lifesavers: a position paper on access to Naloxone Hydrochloride for potential opioid overdose witnesses (2010) Anex, Melbourne, Australia.http://www.atoda.org.au/wp-content/uploads/Anex-2010-Lifesavers-a-position-paper-on-access-to-Naloxone1.pdf.

[2] Straus, M. M., Ghitza, U.E., & Tai, B. (2013). Preventing deaths from rising opioid overdose in the US – the promise of naloxone antidote in community-based naloxone take-home programs. *Substance Abuse and Rehabilitation* (4), pp. 65-72.

(a) **Risks and benefits associated with the use of naloxone**

It is Penington Institute's experience that in Australia, general practitioners have been reluctant to prescribe naloxone to people at risk of overdosing, or to family members of those at risk. Naloxone has historically only been used by medical personnel (eg: qualified hospital staff or paramedics) to reverse the effects of opioid overdose.

In many circumstances, emergency medical help is not sought, for use of opioids, due to the fear of police involvement when illegal substances are being used or because witnesses do not recognise overdose symptoms as life-threatening.[3] In rural settings, emergency help may not arrive in a timely manner to treat an overdose.[5]

While not all opioid overdoses are life-threatening, a significant number of lives could be saved each year if laypeople were able to provide naloxone to overdosing persons who may otherwise not have received medical intervention in time.[4] Naloxone can be administered by minimally trained laypeople without causing any harmful effects.[5]

Additionally, rescue breathing and timely provision of naloxone by a witness of an overdosing incident may help reduce some of the morbidities associated with non-fatal overdose, including brain damage.[6] This is a similar scenario to laypeople administering adrenaline to anaphylaxis sufferers using an EpiPen. The wide accessibility of EpiPens through pharmacies means that potential witnesses of anaphylaxis, such as the family and friends of those with severe allergies, are able to instantly respond to life-threatening situations and save the lives of their loved ones.

International evidence also indicates that providing naloxone, with appropriate training, to opioid users and to potential overdose witnesses such as their family and friends, can result in successful overdose reversal in a safe and effective manner. For example, a US comparative study indicated that providing naloxone hydrochloride and training to drug users, their families and friends involved a reported 10,171 overdose reversals.[7] In December 2011, Australia's first overdose management program was launched in the ACT, providing naloxone on prescription to potential overdose victims. Independent evaluators released an interim findings report on 13 February 2014, assessing the implementation fidelity and participants' experience of

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[3] Center for Health Law, Closing Death's Door: Action steps to facilitate emergency opioid drug overdose reversal in the United States, Center for Health Law, Policy and Practice http://www.ihra.net/files/2010/08/23/Beletsky_-_Closing_Deaths_Door.pdf.

[4] Harm Reduction Coalition; Guide to developing and managing overdose prevention and take-home naloxone projects http://harmreduction.org/wp-content/uploads/2012/11/od-manual-final-links.pdf.

[5] Ibid.

[6] Harm Reduction Coalition; Guide to developing and managing overdose prevention and take-home naloxone projects http://harmreduction.org/wp-content/uploads/2012/11/od-manual-final-links.pdf.

[7] Wheeler E, Davidson, PJ, Jones, TS and Irwin, KS. Community-Based Opioid Overdose Prevention Programs Providing Naloxone (2012) *MMWR. Morbidity and Mortality Weekly Report*, *61*(6), 101–105.

the program.[8] The findings revealed that the 140 program participants evaluated displayed a higher knowledge of overdose identification and response after the completion of the training compared to before. The report also revealed that they were able to administer naloxone in a non-medical setting which resulted in 23 successfully reported overdose reversals. The evaluation concluded that the ACT take-home naloxone program was overwhelmingly positive.

Programs that train potential overdose witnesses to recognise overdose signs, respond appropriately and be provided prescriptions for naloxone are now also operating in Victoria, New South Wales, South Australia and Queensland. With the exception of Victoria, these are still regarded as small scale.

There are very few risks associated with naloxone use. A very small number of people have hypersensitivity to naloxone. The sudden return to consciousness of an overdosing drug user may sometimes be associated with tremor and hyperventilation.[9] Yet, it is not possible to overdose on naloxone. If a large dose is given to a person with opioids in their system, they may experience symptoms of opioid withdrawal. However, this is based on prior dependence on opioids. Naloxone, itself, does not cause physical or psychological dependence.[10]

(b) **The purposes for which a substance is to be used and the extent of use of that substance**

Naloxone is an opioid antagonist able to reverse life-threatening central nervous and respiratory depression caused by opioid overdose. It carries almost no risk.

Naloxone, as a Schedule 4 medicine, may be safely and legally administered by a lay person, but only to the person named in the prescription. The current scheduling limits the potential for more lives to be saved.If there is a provision for the single use injection form of naloxone to be available as an S3 drug the limitation that the drug be only used for named persons is removed. There are circumstances, for example in drug treatment facilities, where the identity of a specific overdose victim may not be known before the event. In these cases naloxone could be legally used by a lay person if it had been obtained as a Schedule 3 drug. In this circumstance, the control point would be with the pharmacist who would be in a position to assess whether the intended use was safe and appropriate.

The below graph shows the number of prescriptions for the UCB minijet which have been processed by the Pharmaceutical Benefits Scheme (**PBS**) since January 2013. It should be noted that some of the emerging (pilot) take-home naloxone programs have been paying for patients' scripts to be dispensed. Prescriptions paid for through such a program would not be taken into account for the below graph. These low numbers

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[8] Key Interim Findings – Independent evaluation of the 'Implementing Expanding Naloxone Availability in the ACT (I-ENAACT)' Program, 2011-2013 - http://www.atoda.org.au/wp-content/uploads/Summary-of-Interim-Findings-summary-for-release-2.pdf

[9] American Society of Health System Pharmacists; AHFS Drug Information 2009. Bethesda, MD. (2009), p. 2252.

[10] American Society of Health System Pharmacists; AHFS Drug Information 2009. Bethesda, MD. (2009), p. 2253.

reveal that there is an urgent need to promote naloxone availability nationally so that the full public health benefit can be realised.

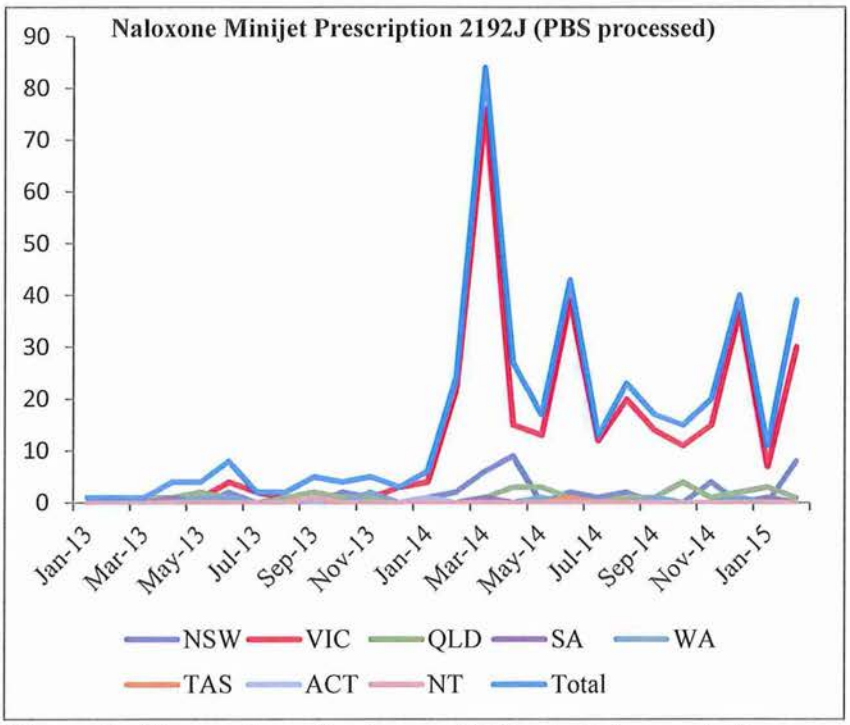

Figure 2: *The number of naloxone UCB minijet prescriptions processed by the PBS*

Under the current proposal, pharmacists would only be able to dispense single-use pre-filled syringes. Penington Institute supports that proposal, on the condition that this formulation remains listed on the Pharmaceutical Benefits Scheme.

(c) Toxicity and safety of naloxone

Naloxone is a safe and effective drug that only works if a person has opioids in their system and has no effect if opioids are absent. People cannot develop a dependency on naloxone. It can be injected into a muscle, vein or under the skin and has a temporary effect that wears off in 30-90 minutes.[11] A study of nine healthy volunteers found that five minutes after the injection of 400µg of naloxone hydrochloride 97% of the dosage was no longer found in the blood serum.[12] This indicates the short duration of action of the drug. This makes it ideal for treating overdose in the community setting.

The risk profile of naloxone is well defined. The safety and risks of naloxone have been previously considered by the TGA and are outlined in Product Information

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[11] Harm Reduction Coalition; Guide to developing and managing overdose prevention and take-home naloxone projects http://harmreduction.org/wp-content/uploads/2012/11/od-manual-final-links.pdf.

[12] Ngai SH, Berkowitz BA, Yang JC, Hempstead J and Spector S, Pharmacokinetics of naloxone in rats and in man: basis for its potency and short duration of action (1976) *Anesthesiology* 44(5) 398-401.

sheets.[13]

Naloxone provision to potential witnesses of overdose is currently occurring in Canada, England, Germany, Georgia, Russia, Scotland, Spain, Norway, Wales, Afghanistan, China, Kazakhstan, Tajikistan, the United States and Vietnam.[14] It has been available over-the-counter in Italy since the 1980s without any reported negative consequences.[15]

(d) **Dosage, formulation, labelling, packaging and presentation of naloxone**

Naloxone is supplied as an intra-muscular injection under the Pharmaceutical Benefits Scheme (PBS) as naloxone (prescriber code 2192J). It is available in a UCB minijet 400µg/1mL solution which is ideal for intramuscular injections.

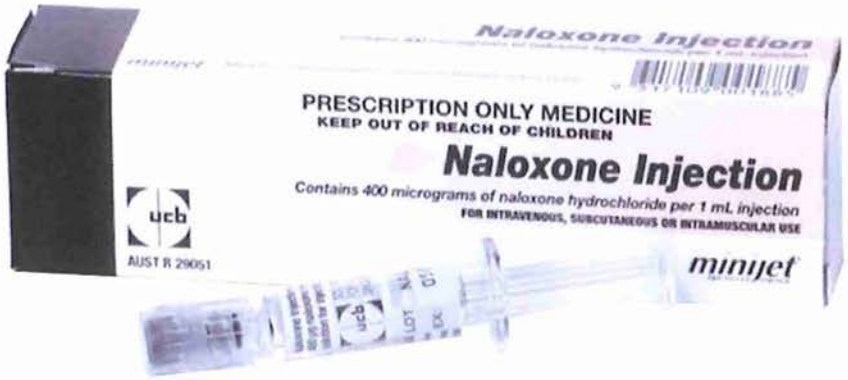

Figure 3: *The packaged form of naloxone proposed to be rescheduled*

Naloxone has a shelf life of approximately two years. An expiry date is printed on the minijet and refers to the last day of the month indicated. The manufacturer of the minijet recommends keeping naloxone in the box until use, out of direct sunlight.

Manufacturers recommend that naloxone be stored below 25 degrees Celsius. However, it is a very sturdy drug and remains effective when stored at temperatures above 25 degrees. It is unlikely that it will degrade to a non-effective level if left in an unrefrigerated or un-air-conditioned space – such as a cupboard or drawer – during summer.

(e) **Potential for misuse/abuse of naloxone**

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[13] Therapeutic Goods Administration (TGA) , Product and Consumer Medicine Information (naloxone) https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=naloxone

[14] Dietze, P and Lenton S, The case for the wider distribution of naloxone in Australia, December 2010 http://www.atoda.org.au/wp-content/uploads/The_heroin_reversal_drug_naloxone_FIN2.pdf

[15] Kim, D, Irwin KS and Khoshnood K, Expanded Access to Naloxone: options for critical response to the epidemic of opioid overdose mortality (2009), Health Policy and Ethics, *American Journal of Public Health* 99(3) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2661437/pdf/402.pdf.

There is no use for naloxone other than for the reversal of the effects of opioids. Therefore, naloxone "has no abuse liability or potential for misuse".[16] Due to this, naloxone has no currency or value on the "black market".

The United Kingdom's Advisory Council on the Misuse of Drugs (ACMD) concluded the following with regards side-effects and misuse potential:

> *"Naloxone brings on temporary withdrawal symptoms in an individual who has opioids in their system, but on people who do not have opioids in their system, there are no such withdrawal effects. Naloxone has no intoxicating effects or dependence-forming potential.*
>
> *"Side-effects are rarely reported. When side-effects have occurred, they were mostly associated with pre-existing medical conditions. (Bryson, 1996; Sporer et al., 2007). They are also associated with significantly higher dose levels than those used in peer overdose interventions" (Advisory Council on the Misuse of Drugs 2012).*[17]

(f) **Other factors relevant to the scheduling of naloxone**

Overdose claimed the lives of 379 Victorians in 2013, alone (including overdoses of alcohol and illegal drugs, as well as pharmaceuticals).[18] This figure is much greater than the road toll which took the lives of 266 Victorians in the same year.[19] According to a Fact Sheet published by the National Coronial Information System (NCIS), the majority of national opioid related deaths across a five year period (2007-2011) were deemed unintentional (71.2% of 4,102 deaths).[20]

The real impact of rescheduling single use naloxone hydrochloride to Schedule 3 is well demonstrated by the following case study from Jersey (US).

> *"A known drug user rushed into the drug clinic demanding that he was immediately given a naloxone minijet to take away. Although agitated, he was resourceful enough to request that the minijet was assembled for him, and he then departed in haste. Some 20 minutes later he returned, accompanied by a shaken overdose victim who had some 15 minutes earlier been comatose and blue. "I was very nervous putting a big needle in him. I didn't know what*

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[16] Straus, MM, Ghitza, UE, and Tai B Preventing deaths from rising opioid overdose in the US – the promise of naloxone antidote in community-based naloxone take-home programs (2013) *Substance Abuse and Rehabilitation* (4), pp. 65-72.

[17] UK Government, The Advisory Council on the Misuse of Drugs, 'Consideration of naloxone' (8 May 2012) (Annexure 2).

[18] Coroners Court of Victoria, Asia Pacific Coroners Society conference 2014 http://www.asiapacificcoroners.org/assets/2014Presentations/0915Dwyer.pdf.

[19] Transport Accident Commission, Road Safety Statistical Summary January 2015 http://www.tac.vic.gov.au/__data/assets/pdf_file/0020/127370/RSSS_Jan15.pdf.

[20] NCIS, Opioid related deaths in Australia (2007-2011), NCIS Fact Sheet August 2014 http://www.ncis.org.au/wp-content/uploads/2014/08/NCIS-Fact-sheet_Opioid-Related-Deaths-in-Australia-2007-2011.pdf.

would happen, what the result would be, but once I did it there was an immediate result that was a good one. He was dead. He came back to life." The overdose victim was then taken by ambulance to the local accident and emergency department where he was observed and made a full recovery."[21]

2.2 CONCLUSION

Overdose, including from opioids, is a leading cause of accidental death, in Australia. External administration of naloxone hydrochloride is able to prevent or substantially reduce the negative health consequences of an opioid overdose. Naloxone is a safe drug to take, which only has effect when there are opioids present in the body. Therefore, it poses no potential for abuse. Naloxone is simple to administer by witnesses of an overdose, with limited instruction.

At present, naloxone is only available to people at risk of overdose, through a prescription. While it is encouraging that there are now some take-home naloxone programs in Australia, the coverage and scale of these programs is limited. There is a need to increase access to this lifesaving drug, as is occurring in a number of nations such as the United States.

It is clear that naloxone is not currently being used to its full potential as an opioid antagonist in overdose situations. Scheduling the single-use pre-filled syringe 400µg/1mL as a Pharmacist Only medication, while maintaining it on the PBS, will increase the options available to community members wishing to receive naloxone. Rescheduling single use naloxone to Schedule 3 of the *Poisons Standard* would greatly reduce barriers to access for the drug.

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[21] Dettmer, K, Saunders B and Strang J, Take home naloxone and the prevention of deaths from opiate overdose: two pilot schemes (2001) *BMJ* 322, pg. 895.

PART 3 – SUPPORTING DATA

Annexure: UK Government, The Advisory Council on the Misuse of Drugs, 'Consideration of naloxone' (8 May 2012).

3. PART 4 – BIBLIOGRAPHY – SEE ATTACHED COPIES

Alcohol Tobacco and Other Drug Association ACT (ATODA) http://www.atoda.org.au/policy/naloxone/.

Alcohol Tobacco and Other Drug Association ACT (ATODA), Key Interim Findings – Independent evaluation of the 'Implementing Expanding Naloxone Availability in the ACT (I-ENAACT)' Program, 2011-2013 http://www.atoda.org.au/wp-content/uploads/Summary-of-Interim-Findings-summary-for-release-2.pdf (**Attachment 1**)

American Society of Health System Pharmacists; AHFS Drug Information 2009. Bethesda, MD. (2009)

Anex, Lifesavers: a position paper on access to Naloxone Hydrochloride for potential opioid overdose witnesses (2010) Anex, Melbourne, Australia.http://www.atoda.org.au/wp-content/uploads/Anex-2010-Lifesavers-a-position-paper-on-access-to-Naloxone1.pdf (**Attachment 2**)

Center for Health Law, Closing Death's Door: Action steps to facilitate emergency opioid drug overdose reversal in the United States, Center for Health Law, Policy and Practice http://www.ihra.net/files/2010/08/23/Beletsky_-_Closing_Deaths_Door.pdf (**Attachment 3**)

Coroners Court of Victoria, Asia Pacific Coroners Society conference 2014 http://www.asiapacificcoroners.org/assets/2014Presentations/0915Dwyer.pdf (**Attachment 4**)

Dettmer, K, Saunders B and Strang J, Take home naloxone and the prevention of deaths from opiate overdose: two pilot schemes (2001) *BMJ* 322, pg. 895. (**Attachment 11**)

Dietze, P and Lenton S, The case for the wider distribution of naloxone in Australia, December 2010 http://www.atoda.org.au/wp-content/uploads/The_heroin_reversal_drug_naloxone_FIN2.pdf (**Attachment 5**)

Harm Reduction Coalition; Guide to developing and managing overdose prevention and take-home naloxone projects http://harmreduction.org/wp-content/uploads/2012/11/od-manual-final-links.pdf (**Attachment 6**)

Kim, D, Irwin KS and Khoshnood K, Expanded Access to Naloxone: options for critical response to the epidemic of opioid overdose mortality (2009), Health Policy and Ethics, *American Journal of Public Health* 99(3) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2661437/pdf/402.pdf (**Attachment 7**)

NCIS, Opioid related deaths in Australia (2007-2011), NCIS Fact Sheet August 2014 http://www.ncis.org.au/wp-content/uploads/2014/08/NCIS-Fact-sheet_Opioid-Related-Deaths-in-Australia-2007-2011.pdf (**Attachment 8**)

Ngai SH, Berkowitz BA, Yang JC, Hempstead J and Spector S, Pharmacokinetics of naloxone in rats and in man: basis for its potency and short duration of action (1976) *Anesthesiology* 44(5) 398-401 (**Attachment 12**)

Penington Institute, Community Overdose Prevention and Education (COPE) Guidelines for naloxone (**Annexure 1**)

Straus, MM, Ghitza, UE, and Tai B Preventing deaths from rising opioid overdose in the US – the promise of naloxone antidote in community-based naloxone take-home programs (2013) *Substance Abuse and Rehabilitation* (4), 65-72 (**Attachment 9**)

Therapeutic Goods Administration (TGA) , Product and Consumer Medicine Information (naloxone) https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=naloxone

Transport Accident Commission, Road Safety Statistical Summary January 2015 http://www.tac.vic.gov.au/__data/assets/pdf_file/0020/127370/RSSS_Jan15.pdf (**Attachment 10**)

UK Government, The Advisory Council on the Misuse of Drugs, 'Consideration of naloxone' (8 May 2012). (**Annexure 1**)

Wheeler E, Davidson, PJ, Jones, TS and Irwin, KS. Community-Based Opioid Overdose Prevention Programs Providing Naloxone (2012) *MMWR. Morbidity and Mortality Weekly Report*, *61*(6), 101–105 (**Attachment 13**)

TGA Consultation: Invitation for public comment – ACMS Meeting, July 2015
NSW Users and AIDS Association (NUAA)
[redacted]

***RE:* proposed amendment to the scheduling of naloxone to include single use prefilled syringe preparation for injection to be included in schedule 3.**

I am writing on behalf of the NSW Users and AIDS Association (NUAA). NUAA is the peak body representing drug users, particularly injecting drug users, in NSW. Opiate users are the key stakeholder group using naloxone. This submission is based on a consultation with our members and represents their overwhelming support for this amendment. Overdose deaths are increasing, with pharmaceutical and poly-drug use accounting for 70% of deaths. [1] Easy availability of naloxone and putting it into the hands of those most likely to witness an overdose is essential in reducing the rates of opioid overdose and other harms related to overdose.

We know from experience that naloxone saves lives - our consultation has collected a number of personal experiences of naloxone users, some of which are detailed here. One of our members is a vibrant, caring, energetic young woman - a mum, a volunteer, committed to the health and human rights of people who are marginalised by our current laws on drug use and sex work. The world would be a much poorer, duller place if she had not been in a situation where naloxone was available when she needed it. Another member has successfully reversed overdoses using naloxone six times in the 11 months since she was trained in its use. She knows that increasing access would save lives – her home is in an area with many people who use drugs and alcohol. They are wary of health services including ambulance call-outs and the police. She often supports her friends and neighbours in the event of an overdose. Because of restrictions on availability, it takes this volunteer up to half a day to replenish her supply of naloxone with no access on weekends. Many people, particularly young people and people in highly marginalised communities are hesitant to call an ambulance in the event of an overdose for fear of attracting the attention of police. One young NUAA member was present at an overdose where the group he was with was reluctant to call for help because of fear of police and parents finding out. Luckily a death was avoided because one person volunteered to remain until an ambulance arrived. In regional and remote areas the possibility of an ambulance reaching a person who has overdosed in time to save a life is lower. Delays and hesitations can cost lives.

These stories are not unique in drug user networks - people continue to die from preventable overdoses. Naloxone is strongly promoted amongst peer networks of drug users, yet access remains

limited. Likewise, as naloxone is currently mostly accessed through take home programs for drug users, people are at present reluctant to carry naloxone for fear of attracting attention. Easily available naloxone would allow friends and family to stock it in their medicine cabinets in case it was needed, just like other lifesaving medications such as ventolin or adrenaline auto-injectors. Instructions for use could be incorporated into First Aid courses.

Naloxone is safe and non-addictive. Most opiate users are familiar with the signs and symptoms of overdose and can administer it safely with little training. Requiring a prescription is an unnecessary burden on the health system and puts people unnecessarily at higher risk of death and brain injury as fronting up at a regular local GP and asking for a prescription is a major barrier to access. Many people who use drugs are reluctant to access services, not only because of perceived or actual stigma and discrimination within the health system, but also because of the delays and costs associated with accessing services. Nationally, there are only a small number of a take home Naloxone programs running. The reach is currently far too limited and naloxone is not being used to its full potential.

Widely available naloxone, an increased focus on peer-led education to reduce the harms of drug use and a community-led campaign to promote the use of naloxone would save lives. For naloxone to reach those most at risk, take-home programs must remain affordable. We ask that the TGA strongly recommend to PBAC that it retain PBS listing. Empowering people to take control of their health may have other health benefits beyond the initial impact of preventing overdose injury and death. Drug users report that rather than enabling risky use, carrying naloxone can raise awareness of the risks of overdose and act as a reminder to use safely. Ideally, naloxone would be available through a variety of settings including opioid substitution clinics and needle and syringe programs. We could then take the opportunity to engage people in their health care, discuss harm reduction and improve access to care.

The feeling of powerlessness as you watch a loved one dying while you're waiting for an ambulance that may or may not get there in time is indescribable. Having naloxone on hand is an extremely empowering and important tool for harm reduction.

<u>Reference:</u>

1. NDARC, 2014: The changing nature of opioid overdose deaths in Australia, https://ndarc.med.unsw.edu.au/resource/changing-nature-opioid-overdose-deaths-australia

TGA Consultation submission ACMS Meeting July 2015

Public consultation on the proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
[redacted] I SUPPORT THE AMENDMENT FOR THE SCHEDULING OF NALOXONE
Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.
Yes I suppot the amendment
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
make a diffrence if over the counter to ~~to~~ save more lives and reduce the risk of overdoses on the street.

TGA Consultation submission May 2015

Submission on proposed amendments to the Poisons Standard (Medicines)

My name is: [redacted]

I would like to submit the following in relation to the proposed amendment for the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Suggested improvements
I support the amendment for the scheduling of naloxone and do not suggest any further improvements
Naloxone is a safe drug. It saves lives and reduces injuries from opioid OD. It's widely available in many other jurisdictions with positive impact and without negative impact. It is easy to give, and has no side effects. Family members, friends, peers and other should have access to it. Just like Epi Pens for anaphylaxis It reduces delay between overdose and treatment. Prescription is unnecessary, and also creates a barrier to access. It is a practical step and needed in the context of ever increasing overdose numbers in Australia. Can be used for injecting drug users, and ANYONE who takes opioid drugs. Should be provided routinely for anyone on opioids.
I support the amendment for the scheduling of naloxone
An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.
• Easy access to naloxone will significantly decrease risk of overdose. • Prompt use of naloxone is critical and there is often a significant time lapse between reporting an overdose and waiting for an ambulance with naloxone to arrive which increases the risk of fatality or brain damage. Response times can be shortened and lives can be saved. • There is often someone else present during an overdose so it makes sense for them to have naloxone. • People do not want to access naloxone from GP as they will have to disclose their drug use and fear discrimination

- Sometimes it can be hard to organise an appt to the Doctors to ask for a prescription of Naloxone. By being able to get it over the counter at a chemist, it means you are much more likely to obtain initial and refill packs in a timely manner

- Naloxone is a safe drug and has no effect on someone with no opioids in their system. You can't abuse it, it has no resale value, it is inexpensive to provide, fast acting and a reliable antidote for opioid overdoses.

- Naloxone is simple to administer by witnesses of an overdose, with limited instruction therefore all persons should be able to administer it with simple instruction from a pharmacist

Advisory Committee for Medicines Scheduling
Meeting July 2015

Response by WA Overdose Strategy Group to invitation for public submission on application to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Closing date for submission – 7 May 2015

[redacted]

Submission to Therapeutic Goods Administration Regarding Rescheduling of Naloxone

To amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3.

Summary of Submission

The Overdose Strategy Group of Western Australia supports the rescheduling of naloxone single use syringe preparations for injection containing 400 micrograms/mL of naloxone (for example Minijet ®) or less in Schedule 3.

The benefits of rescheduling in the manner proposed would be substantial and include widening the availability of naloxone for opioid users; allowing services that work with opioid users to access naloxone and therefore respond to opioid overdose; and the removal of barriers for medical practitioners who may be unwilling to prescribe naloxone due to concerns about naloxone being administered to a person other than whom it was prescribed. This would enhance the ability to prevent and reduce opioid overdose morbidity and mortality, which is an issue of growing concern in Australia.

The risks of rescheduling naloxone appear negligible, as naloxone has no other purpose than to reverse the life threatening respiratory depression associated with an opioid overdose. Naloxone has a high safety profile, with the only contraindication being an allergy to naloxone. It has no psychoactive effects, is short acting and essentially has no effects if used on a person who has not ingested opioids.

Naloxone availability to opioid users is a key strategy of opioid overdose prevention and management in Western Australia along with some other jurisdictions. It has been proven to be an effective strategy in reducing opioid-related fatalities in conjunction with airway management.

While the Overdose Strategy Group is supportive of the application to change the scheduling of naloxone to a Schedule 3 drug, there are several issues to consider. These include the need to ensure that naloxone remains on the Pharmaceutical Benefits Scheme, to avoid increased cost to the consumer; the development of consumer product and administration information; the importance of adequate training to identify and respond to opioid overdose including airway management and

calling an ambulance; and consideration of similar scheduling for naloxone for intranasal administration.

Submission to Therapeutic Goods Administration Regarding Rescheduling of Naloxone

Background: The WA Overdose Strategy Group (OSG)

The WA Overdose Strategy Group (OSG) is convened and chaired by the Drug and Alcohol Office of Western Australia and was established in the late 1990s. The OSG is an interagency collaboration of the Drug and Alcohol Office, Communicable Disease Control Directorate - Sexual Health and Blood-borne Virus Program (WA Department of Health), St John Ambulance Association, Curtin University (National Drug Research Institute), WA Police, WA AIDS Council, Department of Corrective Services, and WA Substance Users Association. It monitors and provides advice about opioid overdose and its prevention in WA. The OSG meets on a quarterly basis contributing quantitative, qualitative and anecdotal data concerning opioid availability and related overdose in addition to providing advice about overdose prevention management strategies.

The OSG aims to be responsive to current opioid trends and a range of anecdotal data is provided to the OSG in confidence, including ambulance call-out data, reports from agencies, treatment episode data and non-fatal opioid overdose attendance at emergency departments of some hospitals, to inform the OSG's work. All anecdotal sources have indicated that the upwards trend of opioid overdose continues to be a cause for concern, for example, recent ambulance call outs exceeding 50 per month. The OSG does not have access to current fatality data.

As a result of the OSG and interagency collaboration, Western Australia has developed and implemented a range of strategies over the last five years to reduce the occurrence of opioid-related fatalities including the provision of overdose prevention training, including providing naloxone hydrochloride to medically suitable opioid users on prescription; training of peers to provide harm reduction education to injecting drug users; and warning labels on sharps containers provided by needle and syringe programs.

Risks and benefits

Naloxone has been used to successfully reverse opioid overdose in Australian medical settings for more than four decades. There is only one contraindication to the use of naloxone, which is hypersensitivity to naloxone. Adverse reactions to

naloxone are generally as a result of precipitating opioid withdrawal and as a result, may include tachycardia, hypertension, dysrhythmias, nausea and vomiting, and diaphoresis. However, naloxone is short acting, usually only lasting 30-120 minutes, and the dose of naloxone used in many peer naloxone programs (400 mcg/mL) is a low enough dose to avoid the negative effects of precipitated opioid withdrawal in most cases.

Nationally and internationally, there have been trends of increasing opioid overdose deaths in recent years. In the late 1990s there was increased attention to the issue of heroin-related overdose as the rates of fatalities soared. In 1999 opioids were involved in 77% of accidental drug-related deaths in Australia[i]. The rate of accidental opioid-related deaths nationally at the peak of the 'heroin crisis' was 101.9[ii] per million persons aged 15-54, and in Western Australia the rate was 84.1 per million of population. This was followed by what has been referred to as the 'heroin drought' from 2001 during which time, the rates of opioid-related deaths dropped as low as 14.1 per million in Western Australia in 2003, and 30.4 nationally in 2007. However, in Australia and particularly Western Australia, the rates of opioid overdose have been trending upwards since the early 2000s. According to the National Drug and Alcohol Research Centre (NDARC), in 2010 the rate of accidental opioid deaths per million of population in the 15-54 year old age group in Western Australia was 65.9 (n=87) in 2010, compared to 54.8 per million (n=71) in 2009. Nationally, the rate of accidental opioid deaths per million of population was 49.5 in 2010 for the same age group, indicating that the rate of accidental opioid fatalities in Western Australia was greater than the national rate. Opioid-related fatalities have been attributed to both the use of illicit opioids and the use and misuse of pharmaceutical opioids.

The benefits of rescheduling in the manner proposed would be substantial. Rescheduling of naloxone will remove the barrier of having to obtain a prescription for naloxone for both opioid users and service providers. 150 opioid users have been prescribed with naloxone as a part of the WA Peer Naloxone Project since 2013. Anecdotally, participants in the WA Peer Naloxone Project have reported that in many cases naloxone is not administered to the person to whom it is prescribed.

Widening the availability of naloxone for opioid users would also increase the possibility of scaling up the WA Peer Naloxone Project. For example, for over 12 months anecdotal reports suggest that Western Australia's Southwest Region has experienced rates of opioid overdose thought to be in excess of other non-

metropolitan regions. The Peer Naloxone Project has been unable to provide naloxone to peers in the Southwest unless they travel to Perth, as it has been difficult to attract a prescriber willing to participate in the project. A number of medical practitioners have expressed concerns about the possibility of naloxone being administered to a person other than whom it has been prescribed. They have indicated that this is a barrier to them participating in the project as they report fearing possible legal impediments. Rescheduling of naloxone will remove this as a barrier for medical practitioners, who may be more willing to consider recommending naloxone to their opioid using patients.

Approximately 50 service providers have attended peer naloxone training and have indicated a desire to have naloxone in their workplace, as they witness opioid overdoses regularly within their services. Currently, workers are unable to access naloxone unless it is prescribed for them. Additionally, as naloxone is a Schedule 4 medication, it is unable to be prescribed except to the person for their own use. Since opioid overdose often results in unconsciousness, naloxone is often administered by someone other than whom it is prescribed. Workers may be disinclined to administer naloxone as a Schedule 4 drug due to concerns about breaches of the WA Poisons Act (1964) and Poisons Regulations (1965). Rescheduling of naloxone to a Schedule 3 drug would reduce barriers to workers accessing and administering naloxone in case of an opioid overdose.

The risks of rescheduling naloxone are negligible, as naloxone has no other purpose than to reverse the life threatening respiratory depression associated with an opioid overdose. Naloxone has a high safety profile, with the only contraindication being an allergy to naloxone. It has no psychoactive effects, is short acting and essentially has no effects if used on a person who has not ingested opioids.

International studies have shown that the administration of naloxone with some interim assisted respiration has prevented death in a number of cases of opioid overdose. The effectiveness of take-home naloxone as an overdose prevention measure was recently reviewed by the European Monitoring Centre for Drugs and Addiction (2015)[iii], who found that naloxone provision amongst opioid users and their peers is an effective strategy to reduce fatal overdose.

Purpose of the substance and extent of use

Naloxone has been used extensively in medical settings, including hospitals and ambulances for over four decades. Since the 1990s there have been calls for increased access to naloxone for opioid users, both overseas and in Australia. In the mid-1990s availability of naloxone was increased in Europe[iv].

In the early 2000s, programs for peer opioid users were established in the United States. Following program evaluations indicating their success at reducing opioid fatalities the number of programs in the US increased. By 2010, there were 188 programs operating in 16 US States[v].

Naloxone is on the World Health Organisation's *List of Essential Medications* and in 2010 the United Nations Commission on Narcotic Drugs urged member nations to incorporate overdose prevention programs, inclusive of naloxone in their national policies.

Since 2012, in response to increasing rates of opioid overdose in Australia, naloxone has been incorporated into opioid overdose prevention programs. These programs currently operate in six jurisdictions; Australian Capital Territory, Western Australia, New South Wales, Victoria, South Australia and Queensland[vi].

Since January 2013, the Drug and Alcohol Office (DAO) has funded the West Australian Substance Users Association (WASUA) to deliver opioid overdose prevention training, including the administration of naloxone to injecting opioid users. WASUA works collaboratively with the Drug and Alcohol Office to deliver the project.

The Peer Naloxone Education Project provides education to recognise and respond to potentially fatal opioid overdose, including the administration of naloxone. The Project is being evaluated by the National Drug Research Institute using similar evaluation methods for naloxone programs in other jurisdictions.

Participants undertake a training session of approximately 2 hours, which provides information on all aspects of opioid overdose prevention and management, including naloxone administration. Typical components include: Review of the causes and how to prevent overdose; assessment and management of an overdose, necessity of calling an ambulance; Basic Life Support; naloxone and its administration including airway maintenance and rescue breathing; post naloxone monitoring and support; and communication with ambulance and police services. Evidence shows such training increases knowledge and skills resulting in safe and effective administration

of the drug. Prior to undertaking the training participants complete a pre-test questionnaire and are invited to complete consent forms for the evaluation of the project.

A consultation with a doctor is made available to participants. The consultation is provided at no cost to the participant. Participants who wish to see the doctor for a naloxone prescription must complete a post-training questionnaire, the results of this indicate whether they understood the content of the training. The doctor undertakes a brief assessment regarding the opioid user's suitability (medically) for naloxone prescription. If the doctor deems the participant suitable, they receive two Minijets® (prefilled syringes) of naloxone hydrochloride 400 mcg/mL and a kit which promotes resuscitation and the safe administration of naloxone. The kit includes a face shield, gloves, sharps disposal container, alcohol wipes, needles, and instructions for CPR and naloxone administration.

In order to ensure that the Project distributes naloxone fairly, the project has set a cap of four prescriptions for 1-2 Minijets®, as required, during a period of 12 months. (Max total eight Minijets® per year will be prescribed free of charge). Participants who have had their eight Minijets® can still be prescribed naloxone, but will have to purchase the naloxone themselves. Naloxone is currently on the Pharmaceutical Benefits Scheme so those who have a health care card will pay approximately $6 for a new two Minijet® supply, or approximately $35-$40 full cost. Several pharmacies have agreed to stock naloxone and not charge a dispensing fee.
Originally the project was confined to one metropolitan area (Northbridge); however, it has since been expanded to another metropolitan area (Fremantle), and two regional areas (Mandurah and Bunbury) to accommodate demand in these areas. Training is conducted monthly in Northbridge and three monthly in other locations. However, as previously stated, it has been difficult to engage a medical practitioner in the Southwest Region (Bunbury).

By the end of 2014, 191 peer opioid users and workers in front-line services such as needle and syringe exchange programs had been trained to recognise and respond to opioid overdose and to administer naloxone. 75% of those who attended the training were prescribed naloxone.

The project team liaises with other jurisdictions that are running similar naloxone projects, and some team members sit on the national naloxone project reference group.

In 2015, it is planned that the naloxone project will be expanded to Acacia Prison, whereby pre-release prisoners who may be at risk of overdose post-release can participate in the training program, and will be supplied with naloxone on their release from prison.

Toxicity

It is not possible to overdose from naloxone. Naloxone administered in large doses to a person who has used opioids will precipitate opioid withdrawal. Administered to a person who has not had opioids it will have no effect. A small number of people experience sensitivity to naloxone.

Dosage, formulation, labelling and packaging of naloxone

Naloxone is currently available in 400mcg/mL Minijets®, a dosage which appears to be suitable for most opioid overdoses. A small number of anecdotal reports from participants of the WA Peer Naloxone Project have indicated that they had to use two Minijets® in order to reverse an overdose. However for the majority of participants 400mcg/mL has been sufficient.

Naloxone available in Australia does not contain consumer information on the use of naloxone. The WA Peer Naloxone Project has developed consumer information on the administration of naloxone, as have other jurisdictions. Therefore, the development of appropriate consumer information would not be a difficult task. Such consumer information should also stress the need for appropriate training on overdose identification and management, including airway support and the need to call an ambulance, due to the fact that people can become re-intoxicated with opioids as naloxone wears-off.

In Western Australia, a training package, including a DVD, is being developed for professionals and opioid users on the identification and management of opioid overdose including the administration of naloxone. Additionally, an online learning package about the administration of naloxone is being developed for health professionals.

The OSG believes that training of consumers and workers in the appropriate identification and management of overdose is needed, irrespective of the scheduling of naloxone.

Intranasal administration devices for naloxone are not currently available in Australia. They have been used overseas with good effect. If they became available in Australia this would make naloxone easier to administer for workers and bystanders/peers alike, and reduce possibilities of needle stick injuries.

The potential for abuse of naloxone

Naloxone does not produce tolerance or dependence and cannot be used for any other purpose other than the reversal of opioid overdose. There is no evidence of potential for the abuse of naloxone.

[i] Australian Bureau of Statistics. (2003). Drug Induced Deaths, Australia, 1991-2001 (Cat. No. 3321.0.55.001)
[ii] Roxburgh, A. and Burns, L.(2014). *Accidental drug-induced deaths due to opioids in Australia, 2010.* Sydney: National Drug and Alcohol Research Centre.
[iii] European Monitoring Centre for Drugs and Drug Addiction (2015), *Preventing fatal overdoses: A systematic review of the effectiveness of take-home naloxone,* EMCDDA Papers, Publications Office of the European Union, Luxembourg.
[iv] Lenton, S. Dietze, P., Degenhardt, L., Darke, S., and Butler, T. (2009) Now is the time to take steps to allow peer access to naloxone for heroin overdose in Australia. *Drug and Alcohol Review,* 28 (6), pp. 583–585. DOI 10.1111/j.1465-3362.2009.00125.x
[v] Wheeler, E., Davidson, P. J., Stephen Jones, T., & Irwin, K. S. (2012). Community-based opioid overdose prevention programs providing naloxone — United States, 2010. *Morbidity and Mortality Weekly Report, 61*, 101-105.
[vi] Lenton, S., Dietze, P., Olsen, A., Wiggins, N., McDonald, D., & Fowlie, C. (2014). Working together: Expanding the availability of naloxone for peer administration to prevent opioid overdose deaths in the Australian Capital Territory and beyond. *Drug and Alcohol Review*, DOI: 10.1111/dar.12198.

Drug Health Services

5 May 2015

South Western Sydney Local Health District
Drug Health Services
Level 1, 7 Levuka Street
Cabramatta NSW 2166

Submission

Therapeutic Goods Administration (TGA) Advisory Committee on Medicines Scheduling

Re: Proposed rescheduling of Naloxone from schedule 4 to schedule 3

Naloxone hydrochloride – referred as 'Naloxone' and known by the brand name Narcan® is a medication which reverses the effect of overdose from opioids such as heroin, morphine, oxycodone, codeine and methadone. Naloxone is an opioid antagonist, reverses opioid overdose by displacing opioid agonists such as heroin, morphine from opioid receptors. Naloxone is the standard treatment for those who have received an overdose of heroin or similar substances. Naloxone acts very quickly and is often a lifesaving in such cases. Naloxone is non-addictive, safe and has no abuse potential as it serves to counter the depressant effects of opioids. Naloxone is short-acting, it can be injected into a muscle, vein or under the skin and has a temporary effect that wears off in 30-90 minutes making it safe and ideal for treating overdoses in the community. Overdose events may not result in death however the lack oxygen to the brain during an overdose can result in lifelong effects including brain injury.

In Australia, naloxone is currently listed as a schedule 4 Prescription Only Medicine. At times, people do not seek emergency assistance in cases of overdose due to the fear of police involvement when illegal substances are used or witnesses do not recognize overdose symptoms as life-threatening. Additionally, emergency assistance may not arrive in a timely manner for people living in rural areas. This in turn creates a barrier to access this life-saving treatment. Naloxone can be administered by minimally trained people without causing any harmful effects which is similar to administering adrenaline to anaphylaxis sufferers using an EpiPen. The wide accessibility of the EpiPen through pharmacies to potential witnesses to anaphylaxis such as family, friends and child care workers are able to instantly respond to life-threatening situations and save lives.

Australia's first overdose management program was launched in the ACT in 2011, providing naloxone on prescriptions to potential overdose victims. The findings revealed that participants were able to identify overdoses and respond appropriately, administer naloxone resulting in 23 successfully reported overdose reversals. This evaluation demonstrated that take-home naloxone program was overwhelmingly positive.

In 1998, opioid overdose in Australia was responsible for 737 deaths and with increased prescriptions of opioids such as morphine since the late 1990's and oxycodone in recent years,

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hospital separations for ‘other opioid’ poisoning between the financial year 2005-2006 and 2006-2007 has doubled.

Overdose does not happen instantaneously, non-fatal overdoses has the potential to cause significant persisting neurological and muscular morbidity further increasing the burden on Australia’s healthcare and pain and suffering for the victims and their families. During the Quarter 1 reporting period 1 January – 31 March 2015 South Western Sydney Local Health District notified seventeen deaths to the Ministry of Health (MoH) as per reporting requirements. Following investigation, seven (7) out of the 17 (41%) deaths were identified as suspected overdoses. This figure only reflects the number of overdoses of clients who were known to the health service during this period of time, and does not take into account other overdose deaths in the community of South Western Sydney throughout this time.

Naloxone distribution has occurred for more than 12 years in the United States. Naloxone provision to potential witnesses of overdose is also occurring in Canada, Germany, Georgia, Russia, Spain, Norway, Afghanistan, China, Kazakhstan, Tajikistan and Vietnam. It has been available over-the-counter in Italy since the 1980s without any reported negative consequences.

Reviews from the United States and European Naloxone distribution programs provide common findings revealing that any person can be trained to identify opioid overdose and effectively reverse the overdose using naloxone. The efficacy of reversing opioid overdose by naloxone is well documented in medical literature. Furthermore, the availability of naloxone does not increase the uptake of opioid use rather it increases access into treatment.

In 2012, The United Nations recommended that ‘opioid treatment, including the provision of opioid receptor antagonist such as naloxone, is part of a comprehensive approach to services for drug users and can reverse the effects of opioids and prevent mortality’. Anex, 2012

Naloxone is the standard treatment for overdose from opioids such as heroin, morphine, oxycodone and methadone to name a few. It has been known as a lifesaver and has reduced opioid overdose-related deaths and morbidity. Scheduling the single-use pre-filled syringe 400µg/1mL as a Pharmacist Only medication, while maintaining it on the PBS, will greatly improve access and improve mortality rates for overdose.

I strongly support TGA consideration of the rescheduling of this life-saving medication and urge the TGA to make this medication more feely available..

Yours sincerely,

[redacted]

[redacted]
Drug Health Services

Reference

Anex (2012), Australian Drug Policy: Lifesavers – access to naloxone to reduce opioid overdose-related deaths and morbidity. Anex, Melbourne, Australia.
http://www.anex.org.au/wp-content/uploads/Australian-Drug-Policy-Lifesavers-access-to-naloxone.pdf

Advisory Committee for Medicines Scheduling
Meeting July 2015

Response by Sydney Medically Supervised Injecting Centre to invitation for public submission on application to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Closing date for submission – 7 May 2015

Suggested improvements

None

Whether or not you support the amendment/s. If you do not support the amendment/s, you may make suggestions for an alternative acceptable to you.

Yes, supported

An assessment of how the proposed change will impact on you.

I write on behalf of the only supervised injecting centre in Australia – the Sydney Medically Supervised Injecting Centre (MSIC). We are a harm reduction health service managed by the social services arm of the Uniting Church. The Sydney MSIC operates under an amendment to the NSW Drug Misuse and Trafficking Act and is licensed through the NSW Ministry of Health and NSW Police. We have over 14 years of operational experience and one of our key aims is to reduce the morbidity and mortality associated with injecting drug use, and to effectively and appropriately intervene in the event of a drug overdose. Indeed in the last 14 years we have managed more than 5000 opioid overdoses onsite without a single fatality.

In late 2014 we rolled out a Take-home Naloxone Program. The Program involves staff identifying a person at risk of opioid overdose (100% of our clients by definition) and providing brief training on the recognition, management and appropriate treatment of an overdose. Clients are assessed at the end of the training on knowledge and competence, and then prescribed and receive 5 x 400mcg prefilled naloxone mini-jets, plus additional equipment and an information sheet. This program follows on from other similar small scale pilot programs conducted elsewhere in NSW.

The context behind this Program is that the Sydney MSIC clearly cannot reach each and every opioid injecting person for every opioid injection. The broader context for Australia is that opioid overdose deaths have been increasing each year for a number of years. Opioid overdoses can be relatively easily treated with appropriate intervention including airway management and naloxone which is a safe and effective medicine.

I would like to explain the practicalities of the current program with naloxone as a Schedule 4. I am the only medical practitioner employed by the Sydney MSIC. Our service is open approximately 80 hours each week and I am employed for 28 hours each week. My ability to personally see all clients for their prescriptions is limited, creating a barrier to our broader distribution of naloxone. On the days I am unavailable, we have a complex and protracted process involving the training of clients, then a phone call to me with a handover. I then contact our local pharmacy to provide a phone order for naloxone and client details, and a follow-up scanned copy of a PBS prescription in the client's name. Then the hard copies of prescriptions are delivered to the pharmacy on my next day at work.

Our registered nursing staff, while they are able to administer intramuscular naloxone in the event of an acute overdose onsite when someone isn't breathing, they are legally *unable* to dispense the medication for take-home use. This creates a needless, time consuming and resource intensive process with unnecessary barriers to its implementation. It also seems simply unnecessary. If naloxone minijets were schedule 3 MSIC staff would be able to deliver client training for take home use whenever the opportunity presented itself, without needing my prescription.

I believe that barriers to wider availability must be addressed if we are to reduce the increasing morbidity and mortality associated with opioid overdose in this country. This applies not only to the injection of opioids but also oral use of prescription opioids – naloxone should be available to anyone who uses opioid drugs/medication and their friends/families/loved ones. These are known as secondary contacts.

The current model of Schedule 4 makes prescribing to secondary contacts very difficult. For example, we would like to provide overdose intervention training for members of Family Drug Support, however under current scheduling regulations I cannot prescribe naloxone to family members unless they themselves are at risk of overdose. The script must be written for the user him or herself. Given the potential for family members to be present at an overdose, and thus available as well as willing to intervene, this seems nonsensical.

This drug is not a drug of abuse. It is non-addictive and safe. It has no effect but to reverse the depressant effects of opiates. Why would we not making this readily available to all that need it?

International data indicate that approximately 20% of take-home naloxone results in a reported reversal. Further, international data indicate that broader availability of this drug has not led to increased opioid use, or to any increased harm, but instead has potentially saved the lives of many hundreds of individuals. I note that in other jurisdictions naloxone is available to police and community workers, where it has had positive results. I also note that the World Health Organisation released their guidelines for the Community Management of Opioid Overdose and in it they specifically recommend increasing the availability of naloxone in the community to people likely to witness an overdose.

We have existing examples of making life saving medication available to those at risk of a rapidly fatal reaction – specifically an Epi-pen for anaphylaxis. Given the safety profile of naloxone, this seems a very obvious drug to schedule at Level 3 and ensure wider availability.

Additionally, an ambulance is not called in every instance of an overdose, even when other people are present. Sometimes there is fear of reprisal or police involvement. Even when an ambulance is called, there is of a delay in the person receiving treatment while the ambulance arrives. A timely response is critical to reduce not only mortality but also morbidity. Early intervention by peers, community workers, family, friends, etc. can greatly reduce risk of brain damage, as well as death from opioid overdose.

In summary, rescheduling the prefilled, single use mini-jets of 400mcg of naloxone would greatly increase the capacity of this drug to be used to its full potential.

One final point is that it is crucially important that financial barriers do not replace scheduling barriers. If any rescheduling is to occur, I would strongly advocate that any naloxone provided in Take Home Naloxone programs is maintained on the PBS.

Australia has always been considered a leader in harm reduction around the world. Scheduling naloxone at level 3 and maintaining its affordability for users would be another example of our commitment to ensuring practical measures are available to reduce the harms associated with opioid use in our community.

Advisory Committee for Medicines Scheduling
Meeting July 2015

Response by Penington Institute to invitation for public submission on application to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Closing date for submission – 7 May 2015

[redacted]

CONTENTS

1. PART 1 – SUMMARY OF SUBMISSION

1.1 PROPOSED SCHEDULING / RESCHEDULING TO THE *POISONS STANDARD*

Penington Institute refers to the invitation for public comment on the application made to amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3

Penington Institute agrees with the proposed rescheduling submitted for public consultation by July 2015, and provides this submission in support of the existing rescheduling application. To ensure that adequate detail has been included in this submission, Penington Institute has used the structure, and fulfilled the requirements of, a rescheduling application.

1.2 SUGGESTED SCHEDULING OR OTHER WORDING

(a) **Schedule 3 – proposed new entry**

NALOXONE in single-use preparations for prefilled injection containing 400 micrograms/mL of naloxone or less.

(b) **Schedule 4 – modified entry**

NALOXONE **except** when included in Schedule 3.

1.3 SUBSTANCE SUMMARY

Naloxone hydrochloride (also referred to simply as ‘naloxone’, and known by the brand name Narcan®) is a type of medication called an “opioid antagonist”. Naloxone (CAS Number 465-65-6) is a life-saving medicine that temporarily reverses the life-threatening depression of the central nervous and respiratory systems that occurs in overdose.

1.4 OVERVIEW

Naloxone hydrochloride is an opioid antagonist that completely or partially reverses the effects of natural and synthetic opioids such as codeine, heroin, methadone, morphine and oxycodone. It is non-addictive and safe, primarily because it does little else but counter the depressant effects of opiates. Since the 1970s it has been used by paramedics and emergency room physicians to reverse the effects of opioids, including in people suffering a life threatening overdose. Thousands of lives are saved and severe brain injuries avoided each year by Australian paramedics who carry it with them as part of standard practice.

As in other parts of the world, there are now some small-scale programs in Australia where potential overdose witnesses (such as opioid injectors) are provided access to naloxone through what are known, in some areas, as ‘take home naloxone’ programs. These programs are conducted, for example, through health services and patients/clients receive a script which can then be claimed against the PBS. Although

Australian programs are quite limited in scale to date, indications are they are successful [1].

A limited rescheduling of naloxone from a Schedule 4 Prescription Only Medicine to a Schedule 3 Pharmacist Only Medicine would assist in providing much needed access to naloxone in the wider community. Pharmacists are highly educated medication specialists who are easily accessible to the public. A rescheduling would allow pharmacists to supply naloxone without prescription, which would assist reduce the number of fatal opioid overdoses in Australia.

2. PART 2 – BODY OF SUBMISSION

2.1 BACKGROUND

Opioids (such as oxycodone, morphine, heroin, codeine and methadone) are central nervous system depressants, which, in the case of overdose, gradually suppress respiration. Without intervention, opioid overdose can lead to permanent brain injury or death [2, 3].

Australia is in the midst of a prolonged problem of accidental and preventable deaths associated with overdose of licit and illicit opioids [4-6].

Naloxone hydrochloride is an opioid antagonist. It works by knocking the opioids off the body's receptors for a short time (around 30 to 90 minutes), as indicated in the diagram below. This is because naloxone has a stronger affinity to the opioid receptors than many opioids [2].

In Australia, naloxone is currently listed as a Schedule 4 Prescription Only Medicine.

Figure 1: *The operation of naloxone*

2.2 CRITERIA TO BE SATISFIED FOR APPLICATION FOR RESCHEDULING (CHANGE TO PART 4 OF THE *POISONS STANDARD*)

(a) Risks and benefits associated with the use of naloxone

It is Penington Institute's experience that in Australia, the naloxone formulation in question has been under-prescribed. General practitioners have been be reluctant to prescribe naloxone to people at risk of overdosing, or to family members of those at risk. Naloxone has historically only been used by medical personnel (eg: qualified hospital staff or paramedics) to reverse the effects of opioid overdose.

In many circumstances, emergency medical help is not sought in response to overdose due to a fear of police involvement when illegal substances are being used, or because witnesses do not recognise overdose symptoms as life-threatening [7]. In rural settings, emergency help may not arrive in a timely manner to treat an overdose [8].

While not all opioid overdoses are life-threatening, a significant number of lives could be saved each year if laypeople were able to provide naloxone to overdosing persons who may otherwise not have received medical intervention in time [9]. Naloxone can be administered by minimally trained laypeople without causing any harmful effects [10, 11].

Additionally, rescue breathing and timely administration of naloxone by a witness of an overdosing incident may help reduce some of the morbidities associated with non-fatal overdose, including brain damage [9]. This is a similar scenario to laypeople administering adrenaline to anaphylaxis sufferers using an EpiPen. The wide accessibility of EpiPens through pharmacies means that potential witnesses of anaphylaxis, such as the family and friends of those with severe allergies, are able to instantly respond to life-threatening situations and save the lives of their loved ones.

International evidence also indicates that providing naloxone, with appropriate training, to opioid users and to potential overdose witnesses such as their family and friends, can result in successful overdose reversal in a safe and effective manner. For example, a US comparative study indicated that providing naloxone hydrochloride and training to drug users, their families and friends involved a reported 10,171 overdose reversals [12]. In December 2011, Australia's first overdose management program was launched in the ACT, providing naloxone on prescription to people at risk of overdose. Independent evaluators released an interim findings report on 13 February 2014, assessing the implementation fidelity and participants' experience of the program [13]. The findings revealed that the 140 program participants evaluated displayed a higher knowledge of overdose identification and response after the completion of the training compared to before. The report also revealed that they were able to administer naloxone in a non-medical setting which resulted in 23 successfully reported overdose reversals. The evaluation concluded that the ACT take-home naloxone program was overwhelmingly positive.

Programs that train potential overdose witnesses to recognise overdose signs, respond appropriately and be provided prescriptions for naloxone are now also operating in Victoria, New South Wales, South Australia, Western Australia and Queensland [14]. Under these programs, people at risk of overdose are being provided scripts and are

dispensed naloxone by pharmacists. With the exception of Victoria, these are still regarded as limited in scope, and also scale.

There are very few risks associated with naloxone use, including that of overdose. A very small number of people have hypersensitivity to naloxone. The sudden return to consciousness of an overdosing person may sometimes be associated with tremor and hyperventilation [15]. If a large dose is given to a person with opioids in their system, they may experience symptoms of opioid withdrawal. However, this is based on existing dependence on opioids. Naloxone cannot cause physical or psychological dependence [15].

(b) **The purposes for which a substance is to be used and the extent of use of that substance**

Naloxone is an opioid antagonist able to reverse life-threatening central nervous and respiratory depression caused by opioid overdose [2].

Naloxone, as a Schedule 4 medicine, may be safely and legally administered by a lay person, but only to the person named on the prescription. The current scheduling does not fully utilise opportunities for more lives to be saved.

If there is a provision for the single use injection form of naloxone to be available as an S3 drug the limitation that the drug be only used for named persons is removed. There are circumstances, for example in drug treatment facilities, where the identity of a specific overdose victim may not be known before the event. In these cases naloxone could be legally used by a lay person if it had been obtained as a Schedule 3 drug. In this circumstance, the control point would be with the pharmacist who would be in a position to assess whether the intended use was safe and appropriate.

The below graph shows the number of prescriptions for the UCB minijet which have been processed by the Pharmaceutical Benefits Scheme (PBS) since January 2013. It should be noted that some of the emerging (pilot) take-home naloxone programs have been paying for patients' scripts to be dispensed. Prescriptions paid for through such a program would not be taken into account for the below graph. These low numbers reveal that there is an urgent need to promote naloxone availability nationally so that the full public health benefit can be realised.

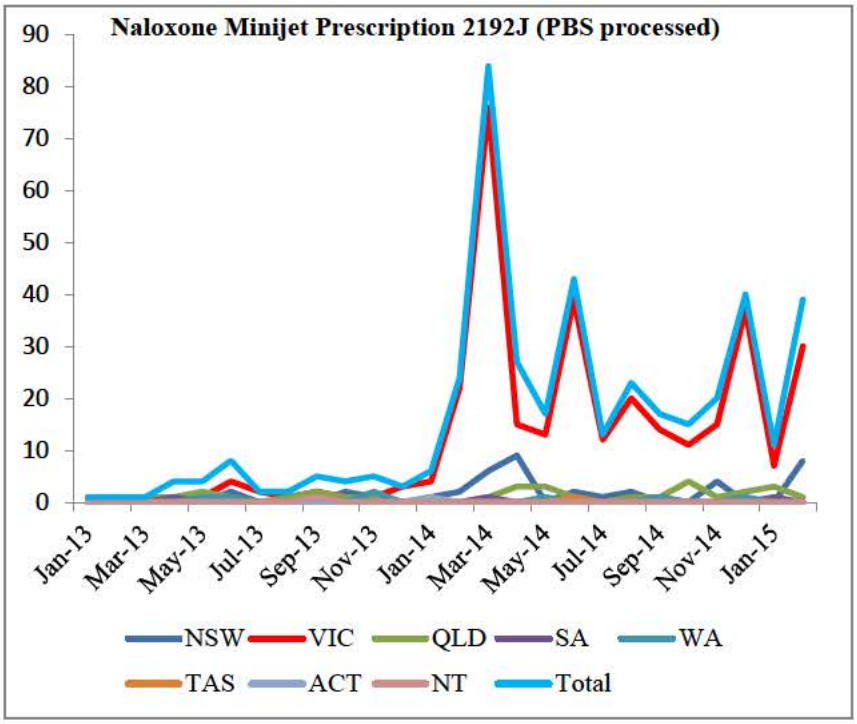

Figure 2: *Naloxone UCB minijet prescriptions processed by the PBS.*

Under the proposal before the TGA, pharmacists would only be able to dispense single-use pre-filled syringes. Penington Institute supports that proposal, on the condition that this formulation remains listed on the Pharmaceutical Benefits Scheme.

(c) Toxicity and safety of naloxone

Naloxone is a safe and effective drug that only works if a person has opioids in their system and has no effect if opioids are absent. People cannot develop a dependency on naloxone. It can be injected into a muscle, vein or under the skin and has a temporary effect that wears off in 30-90 minutes [2]. A study of nine healthy volunteers found that five minutes after the injection of 400µg of naloxone hydrochloride 97% of the dosage was no longer found in the blood serum [16]. This indicates the short duration of action of the drug.

The risk profile of naloxone is well defined. The safety and risks of naloxone have been previously considered by the TGA and are outlined in Product Information sheets [17]. The World Health Organisation recognises that the efficacy and safety profile of naloxone makes it ideal for treating overdose in the community setting [18].

Naloxone provision to potential witnesses of overdose is currently occurring in Canada, England, Germany, Georgia, Russia, Scotland, Spain, Norway, Wales, Afghanistan, China, Kazakhstan, Tajikistan, the United States and Vietnam [9, 19-21]. It has been available over-the-counter in Italy since the 1980s without any reported negative consequences [22].

(d) Dosage, formulation, labelling, packaging and presentation of naloxone

Naloxone is supplied as an intra-muscular injection under the Pharmaceutical Benefits Scheme (PBS) as naloxone (prescriber code 2192J). It is available in a minijet 400µg/1mL solution which is ideal for intramuscular injections.

Naloxone has a shelf life of approximately two years. An expiry date is printed on the minijet and refers to the last day of the month indicated. The manufacturer of the minijet recommends keeping naloxone in the box until use, out of direct sunlight.

Manufacturers recommend that naloxone be stored below 25 degrees Celsius. However, it is a very sturdy drug and remains effective when stored at temperatures above 25 degrees. It is unlikely that it will degrade to a non-effective level if left in an unrefrigerated or un-air-conditioned space – such as a cupboard or drawer – during summer.

(e) **Potential for misuse/abuse of naloxone**

There is no use for naloxone other than for the reversal of the effects of opioids. Therefore, naloxone "has no abuse liability or potential for misuse" [2]. Due to this, naloxone has no currency or value on the "black market".

The United Kingdom's Advisory Council on the Misuse of Drugs (ACMD) concluded the following with regards side-effects and misuse potential:

> *"Naloxone brings on temporary withdrawal symptoms in an individual who has opioids in their system, but on people who do not have opioids in their system, there are no such withdrawal effects. Naloxone has no intoxicating effects or dependence-forming potential.*
>
> *"Side-effects are rarely reported. When side-effects have occurred, they were mostly associated with pre-existing medical conditions. (Bryson, 1996; Sporer et al., 2007). They are also associated with significantly higher dose levels than those used in peer overdose interventions" [23].*

(f) **Other factors relevant to the scheduling of naloxone**

According to the National Coronial Information System (NCIS), the majority of national opioid related deaths across a five year period (2007-2011) were deemed unintentional (71.2% of 4102 deaths) [4]. Overdose claimed the lives of 384 Victorians in 2014 alone [24]. This figure is much greater than the road toll of 249 Victorians in the same year [25].

The Salvation Army's Access Health in Melbourne has been arranging for potential overdose witness to be trained in overdose prevention and response. The program also arranges naloxone prescriptions and dispensing. Several overdose reversals have been achieved by participants. The experience of one participant, who was prescribed naloxone after receiving training at Access Health, highlights the benefit that increased access to naloxone is already providing, and will continue to provide if access is further expanded:

> "I've never overdosed in my life. I don't know why. I've brought back 14 people. I've had 14 people OD in my room and I've had to [use] CPR

> and everything. I used the pens [naloxone minijet] about three weeks ago. There was a chick that was nodding off in my front yard. I could still hear her breathing, but it just got slowly and slowly and eventually her face turned purple so [I injected her]. One pen [minijet] didn't work so I used the other one straight through the clothing"[1] .

2.3 CONCLUSION

Overdose, including from opioids, is a leading cause of accidental death in Australia. External administration of naloxone hydrochloride is able to prevent or substantially reduce the negative health consequences of an opioid overdose. Naloxone is a safe drug which is safe to be administered to people. It only has effect when there are opioids present in the body. Therefore, it poses no potential for abuse. Naloxone is simple to administer by witnesses of an overdose, with limited instruction.

At present, naloxone is only available to people at risk of overdose, through a prescription. While it is encouraging that there are now some take-home naloxone programs in Australia, the coverage and scale of these programs is limited. There is a need to increase access to this lifesaving drug, as is occurring in a number of nations such as the United States.

It is clear that naloxone remains under-prescribed and, therefore, is not currently being used to its full potential as an opioid antagonist in overdose situations. Scheduling the single-use pre-filled syringe 400µg/1mL as a Pharmacist Only medication, while maintaining it on the PBS, will increase the options available to community members wishing to receive naloxone.

Rescheduling single use naloxone to Schedule 3 of the *Poisons Standard* would improve community members' access to this drug and therefore save lives.

PART 3 – SUPPORTING DATA

Annexure 1: UK Government, The Advisory Council on the Misuse of Drugs, 'Consideration of naloxone' (8 May 2012).

3. PART 4 – BIBLIOGRAPHY – SEE ATTACHED COPIES

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Dietze, P and Lenton S, The case for the wider distribution of naloxone in Australia, December 2010 http://www.atoda.org.au/wp-content/uploads/The_heroin_reversal_drug_naloxone_FIN2.pdf (**Attachment 5**)

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Ngai SH, Berkowitz BA, Yang JC, Hempstead J and Spector S, Pharmacokinetics of naloxone in rats and in man: basis for its potency and short duration of action (1976) *Anesthesiology* 44(5) 398-401 (**Attachment 12**)

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Public Health Association
AUSTRALIA

Public Health Association of Australia

Submission to the Therapeutic Goods Administration public consultation on the proposed amendments to the Poisons Standard (Medicines)

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7 May 2015

Contents

Introduction

The Public Health Association of Australia Incorporated (PHAA) is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes. The PHAA has a vision for a healthy region, a healthy nation and healthy people living in a healthy society and a sustaining environment based on prevention, the social determinants of health and equity principles.

Public Health

Public health seeks equitable health for all and goes beyond the treatment of individuals to

[redacted]

The Public Health Association of Australia

PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups concerned with the promotion of health at a population level.

Key roles of the organisation include the development of policy, capacity building and advocacy. Core to our work is an evidence base drawn from a wide range of members working in public health practice, research, administration and related fields who volunteer their time to inform policy, support advocacy and assist in capacity building within the sector. The PHAA is an active participant in a range of population health alliances including the *Australian Health Care Reform Alliance*, the *Social Determinants of Health Alliance*, the *National Complex Needs Alliance* and the *National Alliance for Action on Alcohol*.

PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. In addition to these groups the PHAA is responsible for an outstanding peer review journal - the *Australian and New Zealand Journal of Public Health* (ANZJPH).

Advocacy and capacity building

In recent years PHAA has further developed its advocacy role to achieve the best possible health outcomes for the community, both through working with all levels of governments and agencies, and promoting key policies and advocacy goals through the media, public events and by other means.

Preamble

PHAA welcomes the opportunity to present a submission to the Advisory Committee on Medicines Scheduling (ACMS) as part of the current TGA public consultation on the proposed amendments to the Poisons Standard (Medicines). This is a matter of considerable interest to PHAA as having naloxone more readily available, in the Australian community, has considerable potential for producing good public health outcomes.

This submission is also supported by the Australian Healthcare and Hospitals Association and the Consumers Health Forum of Australia.

Response to public consultation on the proposed amendments to the Poisons Standard (Medicines)

a) The proposal

We understand that the ACMS is seeking submissions specifically addressing the proposal 'To amend the scheduling of naloxone to include single use prefilled syringe preparations for injection containing 400 micrograms/mL of naloxone or less in Schedule 3'. The drug is currently in Schedule 4. We understand that, under the Poisons Standard 2012, Schedule 3 drugs are 'Pharmacist Only Medicine – Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription', and Schedule 4 drugs are 'Prescription Only Medicine, or Prescription Animal Remedy – Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription'. One of the main consequences of the proposal would be for naloxone mini-jets to be sold in community pharmacies without the need for a prescription.

b) Background

We have noted the submission provided by the Penington Institute which includes details about the role of naloxone hydrochloride in the reversing of opioid overdoses, so will not repeat the information set out there. As you know, however, the drug has been demonstrated over many decades to be safe and effective. It is not psychoactive and its only effect in the body is to reverse opioid overdoses.

In the United States, and in some parts of Europe, naloxone is widely available in the community without prescription. There it is used by members of the community, as well as by emergency services personnel, to reverse overdoses. Many lives have been saved in this manner.

WHO states:[1]

> *Opioid overdose is easily reversed with the opioid antidote naloxone and with basic life support. Such care is generally only available in medical settings, however. These guidelines recommend that people who are likely to witness an opioid overdose, including people who use opioids, and their family and friends should be given access to naloxone and training in its use so that they can respond to opioid overdose in an emergency if a medical response is not available.*

Until recently, naloxone was used in Australia almost exclusively by paramedics and in hospital emergency departments. In recent years, commencing in 2012 in the ACT, implementation trials have been conducted into community-based naloxone programs, including those implemented collaboratively between state and territory health departments and drug user organisations. We expect that the first of the evaluations, that of the ACT program, will be released later this year.

[redacted]

those reports in the context of legislative barriers to effective overdose reversal.

c) Rescheduling meets the criteria of suitability for regulatory change as a public health intervention

Naloxone is a product which is ideally suited to enhancing population health through legislative amendment. A recently published paper provides what the authors refer to as 'Criteria for identifying critical opportunities for public health law'.[2] Those criteria are:

- Addresses a problem of public health significance
- The mechanisms underlying the public health problem are sufficiently well understood to support a conclusion that it is plausibly amenable to changes through law
- A plausible legal intervention has been identified.

Amending the regulations covering the availability of naloxone to make it more readily available meets all three criteria, according to the authors and to Australian experience.

d) Availability of naloxone through community pharmacies and other places

The rate of opioid overdose mortality is increasing in Australia. To avoid being in the position that we were in during the late 1990s, with an epidemic of opioid overdose mortality linked to a glut in heroin availability, we need to engage in preventive action now. The community-based naloxone programs being rolled out across the country are important but will be more effective if naloxone is rescheduled so as to become available through community pharmacies and other places, without prescription.

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[1] World Health Organization 2014, *Community management of opioid overdose*, World Health Organization, Geneva.

[2] Mello, MM, Wood, J, Burris, S, Wagenaar, AC, Ibrahim, JK & Swanson, JW 2013, 'Critical opportunities for public health law: a call for action', *American Journal of Public Health*, vol. 103, no. 11, pp. 1979-88.

This implements the core principle of health promotion, namely 'making healthy choices easy choices'. PHAA looks forward to the situation in which people who use opioids, whether illegally or on prescription, and their families, carers and other close associates, have ready access to naloxone for use to reverse an overdose if it occurs. Every potential opioid overdose witness should have easy access to naloxone.

Having naloxone available at community pharmacies, dispensed there without the need for a prescription, but with pharmacists being in a position to advise people on the safe use of the drug, including how to minimise the risk of communicating blood-borne viral infections, is highly desirable.

For effective implementation of the change in scheduling, sponsors should be encouraged to support information and education provision for pharmacists and their support staff.

e) Removing legislative impediments relating to using naloxone to save lives

[redacted] are progressively rolling out community-based naloxone programs, all of which entail a medical practitioner providing a prescription, to a person who uses opioids or to another potential overdose witness, that permits that person to inject the naloxone into themselves were they to experience an opioid overdose. It is obvious, however, that this is not how such programs operate. Instead, a family member, carer or other overdose witness who has naloxone in their possession is going to use the drug to save the life of the person who overdoses. The anomaly is, of course, that this is an illegal act because our Schedule 4 drugs can only legally be administered to the person to whom they are prescribed.

Rescheduling the drug to a Schedule 3, pharmacy-only, non-prescription status, will remove this anomaly and hence remove a legislative barrier to the effective use of the drug to save lives.

f) The financial aspects of availability

PHAA notes that naloxone mini-jets are currently provided, on prescription, under the PBS. This means that their price to consumers is probably lower than what it would be on the commercial market. It has been suggested that rescheduling the drug from Schedule 4 to Schedule 3 could have the consequence of it losing its PBS listing, resulting in its price over-the-counter in community pharmacies increasing markedly. Were this to happen it would introduce significant, problematic, distributional justice concerns. Socially disadvantaged people who use opioids (either on prescription or illegally), and other potential overdose witnesses, may then find it difficult to purchase this life-saving drug, whereas the more well-to-do would have ready access to it. Such an outcome would be contrary to core principles of population health.

Accordingly, PHAA requested that the Advisory Committee, as part of its considerations, identify the likely financial implications of the proposed rescheduling, and take whatever steps are necessary and appropriate to ensure that the rescheduling (which we support) does not result in an increase in the price of the drug to such a level as to become an impediment to accessing it by disadvantaged members of our community.

Conclusion

Thank you for providing an opportunity for PHAA to contribute to this public consultation.

Please do not hesitate to contact PHAA should you require additional information or have any queries in relation to this submission.

7 May 2015