



Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

2 March 2018

To whom it may concern

I am writing in response to the request for submissions on the *Prescription Strong (Schedule 8) opioid use and misuse in Australia – options for regulatory response* consultation paper. The Australian Injecting and Illicit Drug Users League (AIVL) welcomes the opportunity to submit a response to the issues raised within this consultation paper.

Australian Injecting and Illicit Drug Users League

AIVL is the Australian national peak organisation representing the state and territory peer-based drug user organisations and issues of national relevance for people with lived experience of drug use. AIVL's purpose is to advance the health of people who use/have used illicit drugs. This includes a primary focus on reducing the transmission and impact of blood borne viruses (BBVs) including HIV and hepatitis C – including for those accessing drug treatment services - through the effective implementation of peer education, harm reduction, health promotion and policy and advocacy strategies at the national level.

Strengthening responses to prescription opioid misuse and dependency

The consultation paper highlights the issue of increasing fatal overdose related to prescription medications in Australia. As noted within the consultation paper, latest figures on opioid-related overdose in Australia show increasing amounts of overdose related to use of prescription opioids, with medications such as oxycodone, morphine and codeine driving these increasing overdose rates. It is also worth noting that as recently as 2015, fatal overdoses from all drug types doubled the national road toll, with more than 1,400 overdose-related fatalities and 712 fatal car accidents.¹

¹ Penington Institute. (2017). *Australia's Annual Overdose Report*. Penington Institute: Melbourne.

The escalating rates of fatal overdose and other issues raised within the consultation paper highlight the need for a holistic response that moves beyond singular interventions targeting prescribing practices. AIVL recommends that interventions that support enhanced referral pathways and enhanced systemic capacity for people seeking treatment for opioid dependency, as well as increasing availability of Opioid Substitution Therapies, be undertaken in conjunction with any amendments to prescribing practices. The *New Horizons: Review of Alcohol and Other Drug Treatment Services in Australia* report has found that an estimated 200,000-500,000 Australians each year are unable to access support for alcohol and drug issues.² Enhanced access to treatment to manage prescription opioid dependency (to meet current demand) has the potential to intervene before fatal and non-fatal overdose occurs.

Additionally, Opioid Substitution Therapy (OST) systems across each state and territory lack capacity to cater for all people seeking to start substitution therapy, with research suggesting that less than half of Australians who use opioids are currently receiving OSTs. Although a number of factors contribute to this, key amongst these are geographical distance from dosing points and capacity and skills of prescribing GPs to treat clients in need of substitution therapies, particularly in rural and regional areas.^{3 4} Dispensing fees were also cited as a factor affecting the ability of people to stay on OST programs.⁵

In light of limited capacity within the alcohol and drug treatment system and challenges in accessing OSTs treatments to manage opioid dependence, it is critical that these issues be addressed alongside any changes to Schedule 8 prescribing in order to create a holistic response to prescription opioid-related overdose.

Comments on Options for Consideration

Noting our general comments above on the need for holistic responses to prescription opioid overdose, AIVL is also able to provide specific comments on Option 4 (Strengthening Risk Management Plans for opioid products) and Option 6 (Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes).

Option 4: Strengthening Risk Management Plans for opioid products

The consultation paper poses ideas for strengthening risk management plans for opioid products, yet does not make reference to enhancing access to naloxone, an effective overdose reversal medication.

Despite TGA rescheduling of naloxone in 2015 to enable purchasing through pharmacies without a prescription, a number of barriers to accessing this lifesaving medication remain. Chief amongst these are restrictions that prevent naloxone being supplied by anyone other than a GP or pharmacist and a lack of brief intervention training on responding to overdose and how naloxone can be used. At present, community-based training on the use of naloxone is provided through a range of organisations across Australia, however these organisations are unable to provide a supply of naloxone as part of this training, requiring participants to access the medication through GPs at a discounted rate or pay up to \$80 for supply through a pharmacy, thus creating an impediment to access.

² Drug Policy Modelling Program. (2014). *New Horizons: The review of alcohol and other drug treatment services in Australia – Final Report*. National Drug and Alcohol Research Centre, UNSW: Sydney.

³ Lord, S., Kelsall, J., Kirwan, A., & King, T. (2014). *Opioid Pharmacotherapy Fees: A long-standing barrier to treatment entry and retention*. Centre for Research Excellence into Injecting Drug Use, Burnet Institute: Melbourne

⁴ KPMG. (2013). *Review of the Specialist Pharmacotherapy Services*. Department of Health: Melbourne

⁵ Lord, S., Kelsall, J., Kirwan, A., & King, T. (2014). *Opioid Pharmacotherapy Fees: A long-standing barrier to treatment entry and retention*. Centre for Research Excellence into Injecting Drug Use, Burnet Institute: Melbourne

Conversely, although it is recommended that naloxone be supplied in conjunction with training on its use, the accompanying training is unlikely to be universal, meaning that even though the medication is available, family members of people using prescription opioids may not recognise the signs of overdose or know how to administer naloxone.

Enhancing access to naloxone and increasing knowledge of how it can be administered has the potential to decrease rates of fatal opioid overdose. In this context, AIVL recommends further reform to the regulation of naloxone that enhances accessibility of the medication through non-medical sources and recommends that where prescription opioid medications are prescribed, this is done in conjunction with a supply of naloxone and brief intervention training to respond to overdose and administer the medication.

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

The consultation paper proposes to develop additional formulations of opioid-based pain medications that prevent misuse, however research suggest that these abuse-deterrent formulations have little effect on rates of overdose.

Recent research from the National Drug and Alcohol Research Centre suggests that despite the existence of new formulations in oxycodone that prevent crushing and injecting of the medication, this has not resulted in a decrease in fatal overdose or an increase in people seeking treatment for opioid dependency.⁶ In light of these findings, AIVL does not believe that developing additional formulations will have a significant impact on reducing opioid overdose and does not recommend pursuing this option.

Summary Recommendations

AIVL welcomes actions that seek to improve the health of people who use drugs and prevent fatal overdoses. However, in the context of increasing rates of fatal overdose related to prescription opioids, AIVL recommends a holistic response that includes:

- Enhancing alcohol and other drug sector system capacity to enable people to access help and support when they need it
- Enhancing the capacity of Opioid Substitution Therapy systems in each jurisdiction to enable more people to begin and remain on pharmacotherapy treatment programs
- Reforming regulation of naloxone to support provision from non-medical sources, such as community-based organisations
- Ensuring that when opioid prescriptions are provided, this is accompanied with supply of naloxone and brief interventions on responding to overdose
- Avoiding regulatory options that have demonstrated little efficacy in reducing opioid-related overdose, such as new formulations of prescription opioids that prevent misuse.

⁶ Larance, B., Dobbins, T., Peacock, A., Ali, R., Bruno, R., Lintzeris, N., Farrell, M., & Degenhardt, L. (2018). The effect of a potentially tamper-resistant oxycodone formulation on opioid use and harm: main findings of the National Opioid Medications Abuse Deterrence (NOMAD) study. *The Lancet Psychiatry*, Vol. 5(2), 155-166.

Thank you for the opportunity to make a submission to the consultation process. If you would like any further detail on the information contained within our response, please contact James Dunne, Director Programs and Communications, on 02 6279 1600 or at jamesd@aivl.org.au.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Melanie Walker', with a stylized flourish at the end.

Melanie Walker

Chief Executive Officer

Australian Injecting and Illicit Drug Users League