Title: Potential Benefits of Long Acting Buprenorphine Formulations in Pharmacotherapy for Opioid Dependence

Presentation by Melanie Walker, Chief Executive Officer (CEO), Australian Injecting and Illicit Drug Users League (AIVL)
Pharmaceutical Benefits Advisory Committee (PBAC), Sublocade hearing, 13 March 2019

Committee members, colleagues. My name is Melanie Walker and I am the CEO of AIVL – the Australian Injecting and Illicit Drug Users League. Firstly, I would like to thank Bret and the team from Indivior for giving up a good deal of their time today to enable me to talk to you a little bit about the context in which this new treatment option for opioid dependence is being considered.

Who is the Australian Injecting and Illicit Drug Users League (AIVL)?
AIVL is the Australian national peak organisation representing the state and territory peer-based drug user organisations in relation to issues of national relevance for people with lived experience of drug use. AIVL's vision is a world where the health and human rights of people who use/have used drugs are equal to the rest of community.

AIVL's member organisations have a unique level of engagement with their consumers and as such are in a privileged position to be able to provide authentic peer information.

Context of dependence and engagement with treatment
In considering the merits of new Opioid Maintenance Treatments (OMTs) in general, it is important to consider the contexts in which people experience dependence and make decisions about engaging with the current treatment options. Key factors to consider include:

- 'Stability' is concept often referred to in treatment of dependence. However, the relative 'stability' of a person in treatment can be impacted by a variety of external factors and this requires consideration as part of the conversation between a person and their treating clinician in determining the most appropriate treatment option for the individual. For example, someone whose working hours mean that they can't avoid missing doses from time to time; a homeless person regularly relocating; and a person with significant mental health comorbidities may all be considered 'unstable' in terms of their engagement with treatment but for different reasons. Appropriate treatment matching is a matter for individuals and their clinicians – it is important that clinicians have access to a range of evidence-based options so that people are able to choose the treatment that best meets their individual needs in consultation with their treating clinician.

- Dependence is a relapsing, remitting condition – a person in treatment can be getting along very well for a long period of time and then something unforeseen might happen and opioid dependence may again become more difficult to manage. Not surprisingly, the same things that impact the life and behaviour of a person without a history of dependence can equally impact the life and behaviour of a person on treatment for opioid dependence – things like bereavement, relationship breakdown and setbacks at work/loss of employment hit people hard. Life's ups and downs can mean that even the most committed person can have lapses in their engagement with treatment.
- At its best, OMT allows the person to stabilise and in many cases to rebuild their lives, for example by re-entry to the workforce. However, the restrictive nature of OMT programs can act as systemic barriers to these objectives. Due to concerns about the potential for diversion and misuse, OMT programs in all states and territories of Australia have restrictions on the number of take-away doses and require supervised dosing, which can act

as barriers to accessing or remaining on treatment. Although only a minority of consumers divert or misuse opioid pharmacotherapies, it is important to note that all people in treatment are impacted by policies designed to prevent diversion. Even people deemed to be 'stable' for many years in treatment are typically required to have substantial supervision and take-away doses are limited for all people on OMT.

Access and equity issues with the current OMT system

- Costs are substantial and typically not reduced when takeaway doses are prescribed. For instance, in WA there is a great deal of variation in the amount pharmacists charge as a dispensing fee. The bottom of the range is $5.00 -$7.00 per day, ($35.00 to $49.00/week). The top end is around $10.00 per day, ($70/week). As this cost is a dispensing fee, the Medicare safety net does not apply.
- Time lost by individuals can be substantial – a 3-hour return bus ride on multiple days per week would not be unusual in Canberra**,** for those reliant on public transport. All people entering the public OMT system in the ACT are required to attend the public dosing clinic at The Canberra Hospital in Woden while being 'stabilised'. Given the spread out nature of Canberra – the 'bush capital' - and limited bus services to outer suburbs, people's lives can be severely impacted by the constraints of ongoing compliance. Our ACT member organisation knows all too well how this can be a barrier to people seeking 'stability'. Recently, CAHMA assisted a young man to engage with OMT in Canberra. He was doing really well – everyone was happy. But the trip from where he lived to The Canberra Hospital took multiple buses and hours, and it became a significant burden. One day he didn't make the trip. He overdosed and died. As you can imagine tragic events like this impact the whole community. Access to dosing points and inflexible dosing requirements are an issue, even in comparably affluent city areas, and these factors impact on people's access and choices when it comes to engaging with treatment.
- In rural, regional and remote Australia, traveling long distances to reach the nearest dosing point can mean that employment is impossible. Cost and time pressures can therefore affect adherence to dosing or continuation in treatment.
- In addition, requirements for lengthy periods of advance notice for temporary dosing transfers out of area mean that people are sometimes forced to miss doses to manage unforeseen commitments such as family funerals and work trips. Other commitments can conflict with dosing and force a client to miss a dose or consider discontinuing treatment.
- There is a wealth of evidence that daily dispensing fees and requirements for supervised dosing both act as barriers to access and retention in OMT. The requirements around daily supervised dosing create access obstacles for many people in rural and regional areas, people with health or mobility issues, and people in some other areas who are in full time employment. They also make it extremely difficult for people to stay on treatment should they wish or need to travel interstate and especially overseas. AIVL member organisations report numerous cases of people not being able to attend funerals of family members without exiting treatment. The limits on take-away-doses in WA mean that Fly-In-Fly-Out (FIFO) workers cannot currently access buprenorphine or methadone at all. Similar issues affect our peers in every state and territory. For many people in these sorts of situations the option of a depot injection would enable them to access or stay in treatment with minimal disruption to their day-to-day life.
- While there are obvious potential benefits of a depot product – of any persuasion that PBAC deems suitable - for people in rural, regional and remote areas and for those with mobility or access issues in terms of reaching dosing points, overseas travel also continues to present significant problems for those whose work and/or family commitments necessitate it. I recently spoke to a man from Melbourne who had 'jumped off' treatment after being stopped on entry to Japan for work because of his OMT medication. He was shocked and

embarrassed. A couple of months after returning home he had ceased engagement with treatment and was not doing well. He called AIVL to ask if there were any new treatment options on the horizon that might help.

Broader international context: trends and issues

- Each year more than 1,700 Australians lose their lives as a result of an accidental drug overdose[1] , a figure exceeding Australia's national road toll[2].
- The United States (US) is currently responding to an 'Opioid Overdose Crisis'. Every day, more than 130 people in the US die after overdosing on opioids. The U.S. Department of Health and Human Services (HHS) is focusing its efforts on five major priorities, with the first being 'improving access to treatment and recovery services'[3].
- Similarly, in Canada, it is estimated that 2,458 overdose deaths occurred in 2016. In the province of British Columbia — ground zero for the epidemic — more than 1,000 overdose deaths were reported in the first eight months of 2017[4]. Expanded access to drug treatment has again been highlighted as a critical first response.
- Recently reported wastewater analysis in the ACT indicating high levels of pharmaceutical opioids[5] have coincided with a rise in reported overdose deaths. While obviously wastewater analysis is an imperfect indicator and the anecdotal correlation with recent overdose deaths may be coincidence, it has given rise to some concern, given the current international experience. In the absence of an established early warning system for the emergence of new pharmaceutical opioids in the Australian drug supply, the emergence of dangerous pharmaceutical opioids will be difficult to confirm in a timely way. Expanding access to evidence-based treatment options for people currently engaged in – or seeking to engage in – treatment should be front of mind given current international trends in drug supply.

Conclusion

- Decisions related to treatment for opioid dependence cannot be made on simple, arbitrary concepts of 'stable' and 'unstable' but need to consider the whole person including social factors, comorbidities and treatment goals.
- The current framework for medication assisted treatment of opioid dependence has significant impacts on the lives of people in treatment from a dollar cost perspective and time cost perspective.
- These aspects of the treatment framework can influence adherence and engagement with treatment, particularly over time.
- This is relevant to the vast majority of people in treatment as very few are able to access sufficient takeaway doses to avoid these problems.
- Clinicians and people seeking treatment need to have access to a range of evidence-based treatment modalities to maximise the effectiveness of treatment matching.
- Doctors should be able to offer people treatment options that meet their needs and give them the best chance of achieving their treatment goals, no matter where they live in Australia or what their personal circumstances are.

---

[1] Penington Institute: http://www.penington.org.au/australias-annual-overdose-report-2018/

[2] Australian Government Department of Infrastructure and Regional Development: https://bitre.gov.au/statistics/safety/

[3] National Institute on Drug Abuse (US) https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis

[4] Canadian Medical Association Journal: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5770249/

[5] The Canberra Times https://www.canberratimes.com.au/national/act/wastewater-tests-show-canberrans-among-biggest-opioid-users-in-nation-20190219-p50yv1.html

- Any additions to the suite of evidence-based treatments available will expand the range of meaningful treatment choices and options in an environment where these are severely limited by significant barriers for many people currently engaging with – or seeking to engage with – treatment for opioid dependence in Australia.
- Further, current international drug supply trends mean that expanding the range of OMT options to facilitate and enable effective, ongoing engagement for those in and seeking treatment - and those who care for them - is a particularly high priority in the current environment.
- We are asking the Committee to keep these principles and emerging challenges in mind when considering any new OMT options on behalf of the Australian community.