PENINGTON INSTITUTE

Proposed amendments –

Drugs, Poisons and Controlled Substances Regulations 2017 (access controls for MDMA and psilocybine)

May 2023

About Penington Institute

Penington Institute connects lived experience and research to improve community safety in relation to drugs.

It is too easy to judge people who use drugs.

Legal or illegal, the misuse of any psychoactive substance impacts us all.

At Penington Institute, we think it's far more productive to prevent and tackle drug use in a safe, effective and practical way.

Risky behaviours are part of being human.

Our focus is on making individuals and families safer and healthier, helping communities, frontline services and governments reduce harm, respect human rights and improve the rule of law.

Founded by needle exchange workers and people with lived experience of drug use in 1995 as a peak body, The Association of Needle Exchanges (ANEX) grew into Penington Institute, named in honour of Emeritus Professor David Penington AC, who led Australia's early and world-leading approach to HIV/AIDS.

We confront the most important issues and champion innovative evidence-based action to improve people's lives – no matter how challenging our perspective might appear.

A not-for-profit organisation, Penington Institute's research and analysis provides the evidence needed to help us all rethink drug use and create change for the better.

We focus on promoting effective strategies, frontline workforce education and public awareness activities. Our work has a positive impact on people, health and law enforcement systems, the economy and society.

An independent voice of reason on drug policy, we are a straight-talking ally for practical insights, information and evidence-based action for people in need.

Introduction

Penington Institute appreciates the opportunity to comment on *the Proposed amendments – Drugs, Poisons and Controlled Substances Regulations 2017 (access controls for MDMA and psilocybine),* henceforth **the Regulations***.* Below, we have provided responses to the questions included in the consultation paper.

Overall, **we support the proposed amendments to the Regulations and believe they should be accepted.**

If the proposed amendments to the Regulations are accepted, we encourage the Victorian Government to take steps toward addressing the high probability of inequitable access to MDMA- and psilocybine-assisted therapy during the initial period of implementation (which could last years) due to high cost. One important potential step involves consulting with stakeholders to consider the development of a subsidy scheme for access to these treatments.

Consultation Questions

1. **Do you have any comments about the proposed approach to implementing the access controls in Appendix D of the amended Poisons Standard (i.e. restricting prescribing to specialist psychiatrists with Authorised Prescriber approval)?**

Penington Institute endorses the proposed controls, though we note that these should be understood as subject to future reconsideration. Given the gradually accumulating evidence for the efficacy of psilocybin, MDMA, and other so-called psychedelics in treating certain mental health conditions as well as substance use disorders,[1] it is probable that additional indications will merit reclassification to Schedule 8 in the coming years, and that some of these may be compatible with provision of treatment by clinicians other than specialist psychiatrists.

We also call attention to the amendments' potential to create problems of inadequate and inequitable access to these treatment modalities. Accessing psychiatrist-led care in Australia is already characterised by severe workforce constraints[2] and high costs;[3] when the accumulated costs of supervised MDMA and psilocybine protocol development, training, and ethics approval are included, we consider it unlikely that there will be a large number of Authorised Prescribers (AP) offering these treatments for several years.

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[1] Perkins, Daniel, Jerome Sarris, Susan Rossell, Yvonne Bonomo, David Forbes, Christopher Davey, Daniel Hoyer et al. 2021. "Medicinal psychedelics for mental health and addiction: Advancing research of an emerging paradigm." *Australian & New Zealand Journal of Psychiatry* 55 (12): 1127-1133.

[2] Nguyen, Thomas P., and Pravik Solanki. 2023. "Addressing the shortage of psychiatrists in Australia: Strategies to improve recruitment among medical students and prevocational doctors." *Australian & New Zealand Journal of Psychiatry* 57 (2): 161-163.

[3] Davey, Melissa. 'Like hunting for unicorns': Australians on the search for adequate, affordable mental healthcare. *The Guardian*, April 19, 2021. https://www.theguardian.com/australia-news/2021/apr/19/like-hunting-for-unicorns-australians-on-the-search-for-adequate-affordable-mental-healthcare.

Furthermore, clinical protocols for Schedule 8 dispensing and administration for these drugs have not yet been approved, but protocols developed for Australia's increasing number of clinical trials suggest that most Schedule 8 MDMA and psilocybine treatment formats are likely to require multiple steps, creating high costs. These steps include several preparatory sessions; at least one (and possibly two) approved therapists present throughout the 6-8 hour MDMA or psilocybine dosing session (or multiple sessions), in settings specially prepared for administration of these drugs; and multiple follow-up sessions.[4]

Estimated treatment costs of $20,000-30,000 are commonly cited,[5] and Penington Institute consultations indicate that this accurately reflects the cost of at least one ongoing psilocybine-related clinical trial. Subsidisation of these treatments under the Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS) requires multiple steps that will likely require years[6] and still may not cover the full treatment cost. In the absence of these subsidies, high costs will render MDMA and psilocybine-assisted treatment unaffordable for all but the most affluent Australians.

2. **Do you support the proposal to require Authorised Prescribers prescribing Schedule 8 MDMA and Schedule 8 psilocybine in Victoria to notify the Secretary to the Department of Health? If so, why? If not, why not?**

We have no objection to the proposed notification requirement, although consultation revealed concern about the potential increase in regulatory burden that is not required for other medicines and that may not provide clinical benefit.

3. **Do you anticipate Authorised Prescribers in Victoria might have any difficulties with complying with the proposed notification requirements?**

The proposed notification should be viewed in the overall context of the burden of becoming an Authorised Prescriber (AP) and implementing protocols for clinically-managed care – Penington Institute is wary of the likely scarcity of APs due to the overall compliance burden.

4. **Do you support the proposal to limit the direct supply of Schedule 8 MDMA or Schedule 8 psilocybine to the administration to patients in a supervised clinical setting. If not, why?**

Similar to our response to Question 1, in the context of implementing the Therapeutic Goods Administration's February 2023 decision, we support the proposal to limit supply of Schedule 8 MDMA and psilocybine to supervised clinical settings, but reiterate that in the context of probable prolonged period of high treatment costs and lack of Commonwealth subsidies, these amendments

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[4] Australian Government. Australian Clinical Trials. Accessed May 10, 2023.

[5] Chrysanthos, Natassia. 2023. 'It's going to be for people with money': Psychedelic treatment tipped to cost at least $25,000. *The Sydney Morning Herald,* March 21, 2023. https://www.smh.com.au/politics/federal/it-s-going-to-be-for-people-with-money-psychedelic-treatments-tipped-to-cost-at-least-25-000-at-first-20230313-p5crpd.html; Blau, Annika, and Geoff Thompson. 2023. 'Serious concerns' over TGA's decision making on landmark psilocybin, MDMA ruling. *ABC News,* March 18, 2023. https://www.abc.net.au/news/2023-03-18/psychedelic-charity-accused-lobbying-tga-mdma-psilocybin/102103782.

[6] Mihalopoulos, Cathy, Chris Langmead, and Mary Lou Chatterton. 2023. The tricky economics of subsidising psychadelics for mental health therapy. *The Conversation*, May 1, 2023. https://theconversation.com/the-tricky-economics-of-subsidising-psychedelics-for-mental-health-therapy-201462?utm_source=twitter&utm_medium=bylinetwitterbutton

should be subject to revision as evidence accrues of efficacy for a variety of medical conditions and safety in a variety of settings.

5. **Do you have any comments of potential unintended consequences of the proposed amendments to the Regulations?**

As our responses to the preceding questions indicate, our primary concern is the creation of a system that privileges a small set of patients able to pay the high cost of treatment, while the vast majority of potential beneficiaries are excluded.

In this context, we urge the Department of Health to engage in a consultation process with relevant stakeholders including clinicians, potential patients, and patient advocacy groups with an objective of establishing a potential state-level subsidy program for patients who are not benefitting from existing therapies and are unable to pay for Schedule 8 MDMA and psilocybine treatments under the conditions of the proposed amendments. This initiative could be analogous to the existing compassionate access scheme that funds medicinal cannabis provision for paediatric epilepsy patients.[7]

[7] Victorian Department of Health. Information for patients and carers. March 15, 2022. https://www.health.vic.gov.au/drugs-and-poisons/information-for-patients-and-carers