PENINGTON INSTITUTE

Consultation Document – Drugs Poisons and Controlled Substances Amendment (Schedule 9 Poisons) Regulations 2022

Submission

31 August 2022

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.

Like Professor Penington, who remains our Patron to this day, 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

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3. The Victorian Government should develop a compassionate access scheme to fund Schedule 9 drugs that have an evidenced psychiatric benefit to patients with severe mental health disorders.

4. The proposed Schedule 9 patient permit should be replaced with a single trial permit.

5. The Victorian Government should conduct a more comprehensive consultation process before a decision is made about the proposed amendments to the Regulations.

Introduction

Penington Institute appreciates the opportunity to comment on the proposed amendments to the *Drugs, Poisons and Controlled Substances Regulations 2022,* henceforth **the Regulations**. Below, we have provided responses to the questions included in the consultation paper, as well as some general comments about the review process.

Overall, **we do not support the proposed amendments to the Regulations and believe they should not be accepted.**

If the proposed amendments to the Regulations are accepted, we encourage the Victorian Government to implement a compassionate access program, which enables select patients to have access to drugs such as MDMA, DMT and psilocybin for severe mental health conditions, as well addiction treatment.

Penington Institute's submission has been developed following consultation with experts involved in clinical research, clinical mental health practice and pharmaceuticals.

Consultation Questions

1. **Do you support the proposed amendment that ensures Victoria follows the national Scheduling Policy that limits human therapeutic use of Schedule 9 poisons to a controlled clinical trial?**

   Penington Institute does not support the proposed amendments to the Regulations to limit the human use of Schedule 9 poisons to a controlled clinical trial. While drugs such as MDMA, DMT and psilocybin are not currently scheduled for therapeutic use in Australia, a growing body of evidence demonstrates that these drugs, in combination with psychotherapy, can alleviate some mental

health disorders such as depression and post-traumatic stress disorder (PTSD).[1] In addition, emerging evidence suggests these drugs can be used to treat dependencies on alcohol and tobacco.[2]

The proposed changes are therefore regressive and unnecessary given the growth and progress of research regarding the therapeutic benefits of psychedelic drugs. We are concerned that limiting the use of these drugs to clinical trials will take choices about appropriate treatments out of the hands of expert mental health clinicians, many of whom have worked with their patients for years. Furthermore, limiting the use of these drugs to clinical trials will inevitably impact patients' – many of whom suffer with chronic and debilitating mental health conditions – autonomy, choice, and control about their treatment.

There is no evidence that patient safety has been compromised under the existing Schedule 9 permit arrangement that is currently required to prescribe substances such as MDMA and psilocybin. A rigorous process is in place to ensure these substances are only prescribed if certain conditions are met. This includes receiving a SAS-B permit through the Therapeutic Goods Administration (TGA), which is only issued following robust medical review assessing the use of the drug and the patient's individual treatment history and circumstances.

Based on our consultations with experts in this space, Penington Institute understands that in the last 18 months the TGA has issued several SAS-B approvals to patients where other treatment options have failed. We are therefore concerned that the Victorian Government is proposing to block access to substances that are considered medically suitable by the TGA – this has the potential to lead to harms for patients who need these treatments. Further, it is unclear why this change is required given the Department of Health can already deny a Schedule 9 access permit if they believe patient safety is at risk.

Penington Institute believes it is vital that these drugs can be made available to patients in Victoria in special circumstances, where other treatment options have not been successful and where their clinician believes there would be a genuine benefit to their health and wellbeing.

RECOMMENDATIONS:

1. The proposed amendments to the Regulations should **not be accepted** given the growing body of evidence about the therapeutic benefits of some psychedelic substances.
2. Substances such as MDMA, DMT and psilocybin should be made available to Victorian patients in special circumstances.

[1] Jerome, L. et al. (2020). 'Long-term follow-up outcome for MDMA-assisted psychotherapy for treatment of PTSD: a longitudinal pooled analysis of six phase 2 trials'. *Psychopharmacology.* (237). pp. 2485-2497; Mitchell, J.M. et al. (2021). 'MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study'. *Nature Medicine.* (27). pp. 1025-1033; Smith, K.W. et al. (2022). 'MDMA-Assisted Psychotherapy for Treatment of Posttraumatic Stress Disorder: A Systemic Review with Meta-Analysis'. *Clinical Pharmacology.*

[2] Aday. J.S. et al. (2020). 'Long-term effects of psychedelic drugs: A systemic review', *Neuroscience and Bibehavioral Reviews.* (113). 179-189*;* DiVito. A.J. & Leger. R.F. (2020). 'Psychedelics as an emerging novel interventions in the treatment of substance use disorder'. *Molecular Biology Reports.* (47). 9791-9799

2. Do you have any comments on the proposed amendments?

Penington Institute notes that the consultation paper suggests the proposed changes are required as no other Australian state or territory allows access to Schedule 9 substances. However, the Victorian Government has a history of independently establishing their own policies around these issues. For example, prior to medicinal cannabis being down-scheduled to a Schedule 8 substance, the Victorian Government was willing to develop a special access scheme for Victorians to access medicinal cannabis. We suggest that if the proposed amendments to the Regulations are accepted, the government should explore the development of a similar compassionate access scheme, which funds the provision of select Schedule 9 drugs that have an evidenced psychiatric benefit to patients with severe mental health disorders.

We believe such a scheme would strike an appropriate balance between preventing the misuse and abuse of these substances and ensuring that those who would benefit from their controlled use can gain access. Other countries such as Canada[3] and Switzerland[4] are currently moving to expand access to these drugs via compassionate or special access schemes.

This type of scheme would also align with the Victorian Government's commitment to implement all 65 recommendations from the *Royal Commission into Victoria's Mental Health System,* specifically recommendation 64: Driving innovation in mental health treatment, care and support. While there has been no implementation of this recommendation to date, Penington Institute believes the recommendation's goal of implementing and testing new approaches to mental health treatment should include psychedelic treatments such as MDMA, which have been described as a 'breakthrough' for trauma treatment.[5]

Penington Institute is aware that there have been recent high-profile examples of malpractice by some operators administering psychedelic substances to treat PTSD and other conditions, which may be a driving factor behind the proposed reforms. Given these issues, we agree that there must be appropriate checks and balances in place to ensure patient health and safety is protected. However, we do not believe that the proposed changes would deter or stop such practices but could in fact result in additional harms for patients. Substances such as MDMA and psylocibin can be easily accessed via illicit avenues where there is no guarantee of their purity, quality, or safety. This has been recently evidenced by the Canberra drug testing service, which found the purity of 19 samples of MDMA greatly varied from 9 percent to 64 percent.[6] If people in dire need cannot access these substances through legitimate means via their health practitioner, this could drive them to an illicit

[3] Numinus. (2021). 'Numinus announces milestones in compassionate access trial for MDMA-assisted therapy in collaboration with MAPS Public Benefit Corporation'. *Numinus.* 17 Feb. https://numinus.com/news/numinus-announces-milestones-in-compassionate-access-trial-for-mdma-assisted-therapy-in-collaboration-with-maps-public-benefit-corporation/

[4] Oehen. P & Gasser. P. (2022). 'Using MDMA- and LSD-Group Therapy Model in Clinical Practice in Switzerland and Highlighting the Treatment of Trauma Related Disorders'. *Frontiers in Psychiatry.* (13). 1-14.

[5] Feduccia, A.A. et al. (2019). 'Breakthrough for trauma treatment: safety and efficacy of MDMA-assisted psychotherapy compared to paroxetine and sertraline'. *Front Psychiatry.* 10 (650); Mitchell, J.M. et al. (2021). 'MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study'. *Nature Medicine.* (27). pp. 1025-1033.

[6] Roberts. G. (2022). 'What has Canberra's fixed-site pill and drug testing clinic found in its first month'. *ABC.* 25 August. https://www.abc.net.au/news/2022-08-25/act-pill-drug-testing-results-revealed-mdma-heroin/101371644

market, which will undoubtedly increase patients' risk of harm. The development of a compassionate access scheme, particularly for people with severe trauma, would be an important harm reduction mechanism.

RECOMMENDATION:
3. The Victorian Government should develop a compassionate access scheme to fund Schedule 9 drugs that have an evidenced psychiatric benefit to patients with severe mental health disorders.

4. Do you have any comments on the proposed prescribed form for the purposes of a medical practitioner applying for a Schedule 9 permit under section 33A of the Act, included in Appendix 1?

Penington Institute suggests that the proposed individual Schedule 9 treatment permit for every patient involved in a clinical trial should be replaced with a single trial permit. This is the current operating process in New South Wales.[7]

We are concerned that the proposed permit system will create additional workload for researchers when there are already significant requirements that need to be met to conduct research. In addition, if this permit system does go ahead, we query how the Department intends to ensure the privacy of patients involved in clinical trials when collecting their personal information.

RECOMMENDATION:
4. The proposed Schedule 9 patient permit should be replaced with a single trial permit.

General comments

Finally, we would like to comment on our concerns about the consultation process for these proposed amendments to the Regulations.

Some of the stakeholders with whom Penington Institute spoke were not aware this consultation was taking place. There does not seem to be a public-facing platform that is informing interested parties and the public more broadly about the proposed changes and inviting feedback. This raises questions about the transparency of the process and the level of consultation that has taken place.

Given the possible harms that could eventuate from these proposed changes, we suggest a more comprehensive assessment and consultation period should take place.

RECOMMENDATION:
5. The Victorian Government should conduct a more comprehensive consultation process before a decision is made about the proposed amendments to the Regulations.

[7] NSW Health. (2021). 'Licences and authorisations'. *NSW Health.* https://www.health.nsw.gov.au/pharmaceutical/licences/Pages/default.aspx

Conclusion

Penington Institute does not support the proposed amendments to the DPCS Regulations. We believe these amendments are unnecessary and will remove decisions about treatment from expert clinicians and their patients. We are also concerned the proposed amendments may lead to potential harms, namely people accessing these substances via an illicit market.

Victoria has a demonstrated history as a leader in health and mental health reform and innovation. This is evidenced by its push to be the first state in Australia to legalise the use of medicinal cannabis and pass voluntary assisted dying laws. This shows the government's eagerness to provide Victorians with access to contemporary, life-changing treatment options and quality end of life care, which prioritises patient autonomy and choice. Moreover, the Royal Commission into Victorian's Mental Health System and the commitment to implement all of its recommendations further exhibits the government's commitment to supporting Victorians in need of mental health support.

We believe Victoria can continue this tradition by developing a compassionate access scheme to fund Schedule 9 drugs that have an evidenced psychiatric benefit to patients with severe mental health disorders.

Finally, we suggest that a more robust and transparent consultation process must take place before any decisions are made by government about these reforms.