

29 August 2022

Level 11, 257 Collins Street
Melbourne VIC 3000
PO Box 38
Flinders Lane VIC 8009
T: (03) 8662 3300

Medicines and Poisons Regulation Group
Regulatory, Risk, Integrity and Legal Division
Victorian Government, Department of Health
50 Lonsdale Street, Melbourne, VIC 3000

Emailed to: dpcs@health.vic.gov.au

Dear Members of the Medicines and Poisons Regulation Group,

RE: Proposal to restrict permits for Schedule 9 poisons for human therapeutic use under the Drugs, Poisons and Controlled Substances Regulations 2017 to clinical trials approved by a human research ethics committee

Thank you for inviting the Australian Psychological Society (APS) to respond to the current consultation which proposes to restrict permits for Schedule 9 substances for human therapeutic use to Research Ethics Committees approved clinical trials. As with all our work at the APS, we consider our response in light of the Sustainable Development Goals (SDGs)¹. Of particular relevance are SDG 3 “Ensure healthy lives and promote well-being for all at all ages”² and target 16.6 which aims to create “accountable and transparent institutions at all levels”³. The APS supports the proposed amendments to limit the human therapeutic use of Schedule 9 substances to clinical trials as the best way to maximise the safety of patients.

As we have outlined in our Position Statement, *Psychologists and psychedelic-assisted therapy*, the APS welcomes the emergence of safe, evidence-based treatment options. Psychologists are ethically bound by the principles of beneficence and non-maleficence⁴ and must, therefore, ensure that any treatments are conducted with the appropriate safeguards. Schedule 9 substances may, by their nature, present a high risk for misuse. In addition, their therapeutic value is currently undetermined (although we acknowledge that some are undergoing approved clinical trials for the purpose of determining their therapeutic benefit). Given this, we support the amendments which restrict their use in the context of a National Health and Medical Research Council registered Human Research Ethics Committee⁵ which are bound by the National Statement on Ethical Conduct in Human Research⁶. Such restrictions have the following three benefits *inter alia*:

1. Clinical trials are conducted by clinicians and researchers with demonstrable, relevant expertise.
2. Trial protocols require strict procedures to identify and act upon adverse events should they occur. Not only is this in the patient’s best interest, it will help inform the scientific literature of the safety of the substance.
3. Clinical trials will also require an explicit and traceable informed consent process to ensure participants have the best chance in understanding the current scientific knowledge of the drug, the potential side effects, and risks of participating.

As the peak national body representing psychologists, the APS is not in a position to provide detailed feedback regarding the proposed application for a permit as it does not currently affect our profession. We suggest that medical professional associations are asked to comment specifically on the form and implications of the proposed amendments for their professions.

Thank you again for the opportunity to respond to the consultation. If any further information is required from the APS, I would be happy to be contacted through my office on (03) 8662 3300 or by email at z.burgess@psychology.org.au

Kind regards

Dr Zena Burgess, FAPS FAICD
Chief Executive Officer

References

1. United Nations Department of Economic and Social Affairs. (2022). *Sustainable Development*. <https://sdgs.un.org/>
2. United Nations Department of Economic and Social Affairs. (2022). *Goal 3—Ensure healthy lives and promote well-being for all at all ages*. <https://sdgs.un.org/goals/goal3>
3. United Nations Department of Economic and Social Affairs. (2022). *Goal 16—Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels*. <https://sdgs.un.org/goals/goal16>
4. Australian Psychological Society. (2010). *Ethics and practice standards | APS*. <https://www.psychology.org.au/About-Us/What-we-do/ethics-and-practice-standards>
5. National Health and Medical Research Council. (2022). *Human Research Ethics Committees*. <https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees>
6. National Health and Medical Research Council & Australian Research Council. (2018). *National Statement on Ethical Conduct in Human Research (2007)—Updated 2018*. Australian Government. <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1>