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Regulatory Reform Branch
Regulatory, Risk, Integrity and Legal Division
Department of Health
50 Lonsdale Street, Melbourne, VIC 3000

Emailed to: legandregreform@health.vic.gov

Dear Members of the Legislative and Regulatory Reform Team,

RE: Proposed amendments – Drugs, Poisons and Controlled Substances Regulations 2017 (access controls for MDMA and psilocybine)

Thank you for inviting the Australian Psychological Society (APS) to respond to the current consultation which proposes to amend the *Drugs Poisons and Controlled Substances Regulations 2017* (the Regulations) in response to the recent Therapeutic Goods Administration (TGA) announcement. In particular, this relates to the down scheduling of Psilocybin(e) and MDMA (N,α-DIMETHYL-3,4-(METHYLENEDIOXY)PHENYLETHYLAMINE) to be considered Schedule 8 substances in certain situations.

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].

Overall, the APS supports the proposed amendments in an attempt to maximise the safety of patients while Australian and international research is ongoing. In particular, it is important to collect data regarding the safety and tolerability of these substances as these emerging treatments are prescribed in Australia.

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-maleficence[4] and must, therefore, ensure that any treatments are conducted with the appropriate safeguards. Given this, we support the restriction of prescribing psychedelic substances to psychiatrists with Authorised Prescriber Approval. With the emerging status of the substances as treatments of mental ill health internationally, it is appropriate, furthermore, that the prescribing specialist psychiatrist: (a) is registered with an Human Research Ethics Committee, (b) treats according to an approved protocol in an appropriate setting, and (c) is required to submit supply and adverse event reports to the TGA.

In many respects, the prescription of psychedelic substances from July 2023 is akin to very early translational research. Given this, we support the Victorian Government's approach to collect safety and efficacy information as necessary. When considering the specific requirements to inform the Victorian Secretary to the Department of Health, however, we defer to our professional colleagues in

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the Royal Australian New Zealand College of Psychiatrists. However, we acknowledge that it is important to balance safety and identification of misuse and creating a workable solution which is realistic in light of clinical demands. We note that, in general, notification processes that are too burdensome risk poor compliance. We suggest further consultation with potential prescribers to ensure that sufficient and appropriate information is collected.

The APS supports the suggested restriction to limit the direct supply of Schedule 8 MDMA or psilocybin to only be permitted to be administered in supervised clinical settings. This recommendation is in alignment with the TGA report released in 2021 which concluded that "MDMA and psilocybin may show promise in highly selected populations but only where these medicines are administered in closely clinically supervised settings and intensive professional support"[5(p. 5)]. Research evidence is consistent with this assertion, which emphasises that psychedelic substances are tools for therapy, rather than the treatment in and of itself[6]. Given this, the APS would like to strongly emphasise the psychological processes involved in the preparation, delivery [active drug session(s)], and integration of psychological content revealed by psychedelic substances. It is essential that the 'therapy competent' of psychedelic-assisted therapy is clearly articulated in treatment protocols and other documentation. This will ultimately help to elucidate the role that therapy plays in the success of treatment as the substances are used in the wider community.

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

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