VICTORIAN ALCOHOL & DRUG ASSOCIATION

Submission to the Therapeutic Goods Administration's joint-ACCS/ACMS meeting, November 2020

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VAADA Vision

A Victorian community in which the harms associated with drug use are reduced and general health and wellbeing is promoted.

VAADA Objectives

To provide leadership, representation, advocacy and information to the alcohol and other drug and related sectors.

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About VAADA

The Victorian Alcohol and Drug Association (VAADA) is a non-governmental peak organisation representing publicly funded alcohol and other drug services. In Victoria, there are approximately 100 funded alcohol and other drug services of different sizes located across the state.

VAADA aims to support and promote strategies that prevent and reduce the harms associated with alcohol and other drug use across the Victorian community.

Please note: This submission relates solely to the proposed changes to scheduling of psilocybin and MDMA, *not* to other substances listed in the Consultation Paper for the November 2020 meeting of the Therapeutic Goods Administration's Advisory Committees on Chemicals/Medicines Scheduling.

Statement of support

VAADA supports the proposed amendments to the scheduling of Psilocybin and N, α-Dimethyl-3,4-(methylenedioxy)phenylethylamine (**MDMA**) on the Australian Poisons Standard.

Currently, both psilocybin and MDMA are listed in Schedule 9 (Prohibited Substances). The proposal, if approved, would see this scheduling maintained, except when used in the treatment of medical conditions. When used for medical treatment, the substances would be listed under Schedule 8 (Controlled Medicines).

Emerging evidence supports the use of these substances in the treatment of specific medical conditions. As such, Schedule 8 is an appropriate classification for these substances when they are used for approved therapeutic/medical purposes for which there is sufficient evidence regarding efficacy and safety. Given that broader questions drug reform and the legalisation of currently prohibited substances is beyond the scope of this meeting of the ACCS/ACMS, Schedule 9 remains an appropriate listing for the non-medical/therapeutic use of these substances,

VAADA supports the proposed amendments for the following reasons:

- Both psilocybin and MDMA exhibit low harm profiles (Individual and social harms) when compared to other licit and illicit substances;
- The proposed amendments are highly unlikely to result in a significant increase in access to these substances;
- The risk of diversion of these substances for non-medical use as a result of rescheduling is low;
- A listing under Schedule 8 (Controlled Medicines) retains substantial regulatory obligations;

- The proposed amendments will increase opportunities for research into psychedelic-assisted therapy by decreasing the regulatory burden on manufacture, importation, holding, prescription and supply of these substances for approved purposes;
- The proposed amendments allow a high degree of regulatory oversight and control in the following areas: prescription and supply; accreditation of clinical staff to administer/supply; environments for administration; and the development of clinical protocols and guidelines for the medical/therapeutic use of these substances.

However, VAADA's support of the amendments is contingent on the following:

- The therapeutic administration of psilocybin or MDMA is restricted to the treatment of conditions for which there is sufficient evidence for both efficacy and safety.
- The prescription, supply and administration of psilocybin and MDMA is restricted to psychiatrists, specialist addiction physicians and other suitably trained and accredited practitioners such as registered psychologists;
- Appropriate treatment protocols and guidelines are developed to ensure quality control. These place clear limits on dosing, the number of administrations allowed per episode of treatment and restricting the administration to a controlled clinical environment.

Harms of psilocybin

Compared to many of the drugs commonly available for recreational and therapeutic use, psilocybin has an extremely low harm profiles.[1]

Psilocybin is used primarily for recreational and/or spiritual purposes. The pharmacological risks of psilocybin, such as physiological toxicity, habit-forming potential and risk of overdose are extremely low. [2] Social and behavioural harms commonly associated with other substances such as drug-related criminal offending are also very low. A 2011 review of psilocybin harms conducted in the Netherlands concluded that the 'public health and criminal aspects [relating to psilocybin] were negligible'.[3]

[1] Bonomo et al (2019) 'The Australian drug harms ranking study', *Journal of Psychopharmacology*, vol. 33(7).
[2] Amsterdam et al (2011) 'Harm potential of magic mushrooms use: a review', *Regulatory Toxicology and Pharmacology*, vol. 59: 423.
[3] Ibid.

The primary harm associated with psilocybin is the risk of poisoning caused by the ingestion of non-psilocybin-containing mushrooms due to misidentification.[4] That is, the primary harm associated with psilocybin is not caused by psilocybin itself, but by consuming mushrooms that *do not* contain psilocybin. Fatalities where the presence of psilocybin *is* detected are very rare and usually involve concomitant use of other substances.[5]

In Australia, a comprehensive ranking of harms according to drug type ranked psilocybin (in a combined category with LSD) 20th out of 22. Psilocybin/LSD received a combined aggregate score of 5/100. The two substances with lower scores were electronic nicotine devices (e-cigarettes) and kava.[6]

Harms of MDMA

Compared to psilocybin, MDMA has a more significant harm profile. Harms associated with MDMA include overdose (including fatal overdose), and potential for the drug to interact with other substances (like alcohol or medications that increase serotonin levels) or exacerbate other conditions (such as dehydration). MDMA is not considered habit-forming compared to other habit-forming drugs like amphetamines or opioids.

Between 2001-2018, there were 392 MDMA-related deaths in Australia. Two-thirds of these were caused by drug toxicity (48% multiple drug toxicity including MDMA and 14% MDMA toxicity alone). The remaining third were fatal accidents or misadventures in which MDMA was a contributing factor.[7]

Acute MDMA harms are associated with a combination of factors. These include variations in strength (purity and/or amount of MDMA in a specific pill or batch of pills); highly toxic substances (such as *N*-Ethylpentylone) mis-sold as MDMA; naiveté about MDMA contributing to behaviours that increase the risk of harms; and using MDMA in conjunction with other drugs such as alcohol. MDMA is toxic and poses a risk to the health of users. These risks are exacerbated by its unregulated status; meaning quality and supply are not controlled, and health advice may not be available.

[4] National Drug and Alcohol Research Centre (2016) 'Magic mushrooms': https://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/NDA073%20Fact%20Sheet%20Magic%20Mushrooms.pdf
[5] Amsterdam et al (2011).
[6] Bonomo et al (2019).
[7] Roxburgh and Lappin (2019) 'MDMA-related deaths in Australia 2000-2018', *International Journal of Drug Policy*, vol. 76.

In the Australian drug harm study mentioned previously, MDMA was ranked 18 of 22 with an aggregated score of 7/100. Alcohol was ranked first (77/100) and crystal methamphetamine was ranked second (66/100).[8]

In a similar UK study ranking twenty drugs by harm, MDMA (referred to as 'ecstasy') and psilocybin (referred to as 'mushrooms') were ranked 17th and 20th respectively. 'Mushrooms' received a score of 6/100 and 'Ecstasy' a score of 9/100. Alcohol, ranked first, scored 72 and heroin, ranked second, scored 55.[9]

When compared to licit drugs such as alcohol and some pharmaceutical medicines (i.e. opioids) and other illicit drugs such as heroin or methamphetamine, psilocybin and MDMA do not pose a significant risk to Australia's public health.

Evidence of therapeutic benefits

Research into the therapeutic use of various drugs including psilocybin and MDMA has been heavily constrained by the prohibitionist and abstentionist politics of the US. Restrictive amendments to the *US Food Drug and Cosmetic Act 1938* in the 1960s effectively halted research into therapeutic and medical applications of psychedelics. Australia and other countries followed suit, adopting similar legal classifications for these substances.

As a result, while the harms of these drugs have been well documented (and oftentimes overstated or misattributed), the potential benefits of regulated therapeutic access to these substances has not been sufficiently explored. However, emerging evidence for the use of psilocybin and MDMA in the treatment of various mental illnesses is promising.[10]

Recent studies of note include twin experiments conducted at John Hopkins and New York Universities on people recently diagnosed with terminal cancer.[11] [12] In 80% of patients, a single dose of psilocybin administered with a course of psychotherapy led to substantial reductions in anxiety,

[8] Bonomo et al (2019).
[9] Nutt et al (2010) 'Drug Harms in the UK: a multicriterion analysis', *The Lancet*, vol. 376.
[10] Begola and Schillerstrom (2019) 'Hallucinogens and their therapeutic use: A literature review', *Journal pf Psychiatric Practice*, vol. 25.
[11] Griffiths et al (2016) 'Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: a randomized double-blind trial', *Journal of Psychopharmacology*, vol. 30.
[12] Ross et al (2016) ''Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial', *Journal of Psychopharmacology*: vol.30.

depression and 'existential distress'. These results persisted for at least six months. Other research has indicated that psilocybin may be effective in treating addiction and other conditions.[13] [14]

Studies on MDMA-assisted psychotherapy have similarly promising results. MDMA has been found effective in treating Post-Traumatic Stress Disorder.[15] [16] Benefits are not limited to symptom reduction but include cognate benefits such as improved connection with therapist, improved personal relationships and increased feelings of general 'openness' and wellbeing.[17] [18] [19]

In sum, not only have significant therapeutic benefits been detected in the therapeutic application of psilocybin and MDMA but evidence indicates that benefits may be achieved more quickly and last longer compared to orthodox pharmacological treatments currently available (i.e. tri-cyclic anti-depressants, SSRIs, typical and atypical anti-psychotics).[20] [21] Furthermore, several studies have detected benefits for difficult-to-treat conditions such as treatment-resistant depression.[22]

Constraints on supply and administration

Given the modesty of the proposed changes to scheduling of psilocybin and MDMA (Schedule 9 except where listed in Schedule 8), the regulatory constraints on manufacture, supply, importation and prescribing are largely already in place.

Schedule 8 carries a substantial regulatory burden and allows limitations to be put in place on individual items. For therapeutic psilocybin and MDMA for medical treatment, prescription and supply should initially be limited to psychiatrists, specialist addiction physicians other suitably trained and accredited practitioners such as registered psychologists. In addition, administration of

[13] Johnson et al (2014) 'Long-term follow-up of psilocybin-facilitated smoking cessation', *American Journal of Drug and Alcohol Abuse*, vol. 43.
[14] Pollan (2018) *How to change your mind: The new science of psychedelics*, Ch. 6 'The trip Treatment: Psychedelics in Psychotherapy', London: Penguin.
[15] Mithoefer et al (2018) 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy for post-traumatic stress disorder in military veterans, firefighters, and police officers: a randomized, double-blind, dose-response, phase 2 clinical trial', *The Lancet*, vol. 5(6).
[16] Ot'alora et al (2018) '3,4-methylenedioxymethamphetamine-assisted psychotherapy for treatment of chronic posttraumatic stress disorder: A randomized phase 2 controlled trial', *Journal of Psychopharmacology*, vol. 32(12).
[17] Sessa (2017) 'MDMA and PTSD treatment: PTSD: From novel pathophysiology to innovative therapeutics', *Neuroscience Letters*, vol. 649.
[18] Yazar-Klosinki (2016) 'Potential Psychiatric Uses for MDMA', *Multidisciplinary Association for Psychedelic Studies*, vol. 101.
[19] Wagner (2019) 'Combining Cognitive-Behavioural Conjoint Therapy for PTSD with 3, 4-Methylenedioxymethamphetamine (MDMA): A case example', *Journal of Psychoactive Drugs*.
[20] Johnson and Griffiths (2017) 'Potential Therapeutic Effects of Psilocybin', *Neurotherapeutics*, vol. 14.
[21] Wagner et al (Therapeutic effect of increased openness: investigating mechanism of action in MDMA-assisted psychotherapy', *Psychopharmacology*, vol. 31(8).
[22] Johnson and Griffiths (2017).

therapeutic doses should be restricted to controlled clinical environments. As further evidence emerges, these restrictions can be adapted as necessary and appropriate.

Risks associated with proposed changes

Psychedelics are widely acknowledged (by both their proponents and detractors) as among the most powerful psychoactive substances known. Of course, there will always risks involved with adjusting the regulatory constraints on these kinds of substances.

However, these risks can be heavily mitigated with effective regulatory requirements encompassing the manufacture, preparation and administration of therapeutic doses of psilocybin and MDMA. The *Narcotic Drugs Act 1967* and the *Therapeutic Goods Act 1989* constitute an appropriate regulatory burden on the manufacture, importation and supply of pharmaceutical psilocybin and MDMA. Furthermore, the market for therapeutic versions of these substances is likely to remain niche compared to other medicines such as pharmaceutical opioids. As such, the risk of widespread harms arising from therapeutic doses of these drugs is minimal.

A process of accreditation should be developed by appropriate and recognized bodies, such as the Australian Medical Association, Royal Australian and New Zealand College of Psychiatrists (**RANZCP**) and Australian Psychological Society in collaboration with the Australian Health Practitioner Regulation Agency, and guided by the clinical standards of the National Health and Medical Research Council. This will ensure that clinical staff providing psilocybin- or MDMA-assisted therapy have appropriate qualifications, skill and training. The development of a special accreditation for psychedelic-assisted therapy is an option. If developed, this should require successful completion of an independently developed training component. The accreditation process must comprise more than just the payment of a licensing fee.

Rescheduling

VAADA notes that the RANZCP does not support the proposed changes to scheduling. They have stated that more research is needed regarding the safety, efficacy and effectiveness of psychedelic therapies to justify changes to current scheduling. The proposed rescheduling will increase the opportunity for Australian research amid an expanding body of supportive evidence for the therapeutic use of drugs that, again, exhibit very low harm profiles.

The proposed amendments do not constitute a fundamental shift in current regulatory arrangements. Schedule 8 is the highest regulatory classification for therapeutic medicines in

Australia. As such, they will not result in a sudden or significant increase in unregulated access to these substances.

VAADA is confident that current regulatory arrangements for Schedule 8 and the development of an adequate accreditation process for health practitioners to administer psilocybin or MDMA in a therapeutic setting will provide sufficient protections for those want to engage in psychedelic-assisted therapy and the broader Australian community.