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Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

By email: medicines.scheduling@health.gov.au

Application to Reschedule N, α -Dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) from Schedule 9 to Schedule 8 of the Poisons Standard

As the Mental Health spokesperson for the Greens NSW, I make this submission in full support of the proposed amendments to the Poisons Standard that seek to reschedule N, α -Dimethyl-3, 4-(methylenedioxy)phenylethylamine (MDMA) from a Schedule 9 substance to a Schedule 8 substance on the basis of its therapeutic potential, low risk to public health and the current need for new alternatives to existing pharmaceuticals.

Contemporary environmental and health events have posed unique and unprecedented stressors on the population of NSW and the rest of Australia. Stakeholders and individuals are demanding access to new treatments in response to community mental health needs, such as PTSD, addiction and major depression. In some cases, patients and their families have reached out to us for political representation on the matter after exhausting all other treatment options.

MDMA has been receiving international scientific attention and yielding promising results in clinical trials conducted by leading universities. It has also been proven to be safe, non-toxic, and non-addictive in clinical settings (MAPS, 2019). Many other jurisdictions are providing therapeutic access to MDMA in response to these characteristics, and these amendments are an opportunity for Australia to stay abreast of scientific developments and improve its long term mental health outcomes.

The state of mental health in Australia

According to the Australian Bureau of Statistics, around 45% of Australian adults have experienced a mental health disorder at some point in their life ("4824.0.55.001 - Mental Health in Australia: A Snapshot, 2004-05", 2018). Of course, this measure of the 'lifetime' prevalence of any form of mental illness is much higher than reported rates for 'current' diagnosis, with the prevalence of Common Mental Disorders (CMD) amongst working age Australians reported to be 12.2% as of 2014. This figure has remained relatively stable over the years, dropping only slightly from 13.3% in 2001 (Harvey et al., 2017). Nevertheless, this figure represents a large number of working age Australians, inviting further consideration of the treatment provided, and resources afforded to mental health conditions in this country.

Increases have also been seen in the use of pharmaceutical medication to treat mental health conditions. Between the years of 1990 and 2002, there was a 352% increase in the reported use of antidepressants in Australia, and from the years 2000 to 2011 there was a 95% increase (Jorm, Patten, Brugha, & Mojtabai, 2017). It is significant that, while there has been growth in both the resources allocated for mental health treatment and the use of antidepressant medication to treat mental health disorders, there has not been a significant decrease in the prevalence of mental health disorders.

In light of these figures, it is important that every consideration be given to treatments which display efficacy in treating any mental health illness. In this regard, psychedelics are showing a huge amount of promise.

MDMA in the treatment of mental health conditions

MDMA is showing encouraging results in treating various mental health disorders. The area in which MDMA is showing the most promising results is for the treatment of Post Traumatic Stress Disorder (PTSD), a disorder that is associated with high levels of suicide and self-harm. There are only currently two pharmacological treatments approved for PTSD by the FDA: sertraline and paroxetine, with both giving only a slight improvement in symptoms (Mithoefer, Wagner, Mithoefer, Jerome, & Doblin, 2011). For example, the use of sertraline caused only a 10.2 point decrease in the Clinician Administered PTSD Scale (CAPS) score. To put the efficacy of MDMA in treating PTSD in context, one study showed the use of MDMA caused a 53.7 point reduction in CAPS score (Mithoefer et al., 2013). Further, in phase II of this study, 2 months after being treated with MDMA, 55% of

the chronic PTSD subjects no longer met the PTSD Diagnostic criteria, and after 12 months, 66.2% of the participants were in remission (Mithoefer et al., 2011).

MDMA is also thought to have antidepressant effects and can give immediate relief from a depressive state (Majumder, White, & Irvine, 2012). It has been shown that people with a predisposition to depression can have a 'significant decrease in the intensity of depressive symptoms', which is why it has been shown to be the drug of choice for some people (Majumder et al., 2012). As well as alleviating depression, MDMA is known for its pro-social effects and causing an increase in empathy, which was observed primarily in men (Hysek et al., 2014). This may be due, in part, to MDMA causing diminished responses to stimuli deemed as threatening, and to enhancing responses to rewarding social signals (Bedi, Phan, Angstadt, & de Wit, 2009). For people with social anxiety, MDMA can reduce the fear sometimes associated with socialising, and have a positive reinforcement effect, as there will be a positive perception of emotional stimuli.

MDMA safety profile

MDMA has been the recipient of much negative press due to reported deaths associated with its use. However, there has been some suggestion that the different enantiomers of MDMA may be responsible for the various side effects. That is, separating the enantiomers may mean that the positive effects of MDMA may be accessed, without the associated negative (and possibly dangerous) side effects. In a recreational capacity, the MDMA that is being used is a mix of both the S and the R enantiomer, being SR-MDMA (Curry, Young, Tran, Daoud, & Howell, 2018). It has been shown the S enantiomer of MDMA (S-MDMA) may be responsible for the negative side effects of MDMA such as neurotoxicity and hyperthermia (Curry et al., 2018). The R enantiomer is thought to have the pro-social effect that is commonly seen with MDMA, without the risk of negative side effects (Curry et al., 2018). This discovery indicates it may be possible to create a molecule with all the benefits of MDMA, which can be used safely.

Aside from the concerns of MDMA use in the short-term, such as the aforementioned neurotoxicity and hyperthermia, there has been mention of possible serotonergic neurodegradation associated with MDMA use, which may lead to depression in the long term. However, new research from a recent longitudinal study (over 24 months) shows that both active and moderate users of MDMA show low and declining levels of depressive symptoms (Falck, Wang, & Carlson, 2008). That is, despite using MDMA either regularly or moderately over 24 months, the users did not have any lasting depression, indicating MDMA may not have any long-term effect on mood. Research showing a lack of long term

safety concerns related to MDMA use, and the ability to ensure the safer enantiomer of MDMA is used may mean there is the possibility of creating a safe, effective molecule with immediate antidepressant effects, which is desperately needed to give immediate relief.

MDMA internationally

Early access schemes for MDMA-assisted psychotherapy have been approved in the USA, Israel and Switzerland in recognition of the strong evidence base and patient need. In 2017, the FDA granted Breakthrough Therapy Designation to MDMA for the treatment of PTSD. This designation is granted to treatments for serious or life-threatening disease, as well as demonstrating substantial improvement over existing therapies. This designation by the FDA is testament to the benefits people are obtaining from the use of MDMA in the treatment for PTSD.

Australians should be afforded access to potentially life-saving medications and have a chance at recovery from serious mental health conditions. Improving mental health outcomes will also have a positive impact on other societal issues, such as family violence, substance abuse, homelessness, unemployment and the economy.

The combined evidence supporting the safety and efficacy of MDMA along with the international trend towards therapeutic access are strong arguments in favour of the rescheduling amendments. Therefore, the Greens NSW strongly recommend the approval of the proposed amendments.



Cate Faehrmann MLC

On behalf of the NSW Greens