# SAS-B Application Cover Letter

DATE

Contact person: INSERT NAME OF PSYCHIARTRIST OR GENERAL PRACTITIONER/PHYSICIAN AND QUALIFICATIONS

Medicine name: of 3,4-methylenedioxymethamphetamine (MDMA)

Indication: Post Traumatic Stress Disorder (PTSD)

Attached Documents

1. Curriculum Vitae of applicant
2. SAS-B Application Form
3. Patient consent form
4. Treatment protocol overview
5. FDA approved MDMA for PTSD Phase 3 protocol
6. References

To Whom it May Concern,

This submission is an application to prescribe 3,4-methylenedioxymethamphetamine (MDMA) for the treatment of Post-Traumatic-Stress-Disorder (PTSD) in combination with psychotherapy under the Special-Access Scheme Category B. MDMA-assisted psychotherapy gained US Food and Drug Administration (FDA) ‘Breakthrough Therapy Designation’ in 2017 due to results of research trials conducted by the Multidisciplinary Association for Psychedelic Studies (MAPS). I myself, have consulted with Mind Medicine Australia in regards to specific education around the safe and effective provision of MDMA along-side psychotherapy, specifically for PTSD.

**EXAMPLE:** The reason for this application is to address the desperate need of my at-risk patient XX, in the opinion of their medical team, have exhausted clinically appropriate treatment options within RACGP and best practice guidelines. The consequence of not having found a helpful treatment results in; increasing disability for XX, deteriorating social and family integration as well as increasing health system costs.

There are a variety of treatment options for PTSD, of those currently available, trauma focused psychotherapy has been shown to be the most efficacious. Trauma focused psychotherapy modalities include; Trauma-Focused Cognitive-Behavioural Therapy (TFCBT); and Eye Movement Desensitization and Reprocessing (EMDR); Exposure Therapy (ET) and Somatic Experiencing among others. Despite this, of those entering treatment, only 44% of patients experience any clinical improvement in their PTSD symptoms from trauma focused psychotherapies. This figure is significantly less for remission. A significant impediment to the treatment of PTSD with psychotherapy is the high drop-out rate ranging from 30-50% across clinical trials, significantly higher than other mental health disorders.

Pharmacotherapy using antidepressant’s (such as selective serotonin reuptake inhibitors (SSRIs)) is often ineffective. Of those diagnosed with PTSD between 20-30% respond to pharmacotherapy (Hoskins et al. 2015) hence, they are not recommended as first line treatment options by the World Health Organisation.

MDMA-assisted psychotherapy is emerging as a promising treatment for PTSD internationally, research is now progressing to Phase 3 internationally. The treatment involves in-clinic administration of medicinal MDMA alongside psychotherapy and has been found to lead to complete remission in 54.2% of patients in recent significant Phase 2 trials. These patients suffered from PTSD for an average of 18 years. Across these Phase 2 studies the dropout rate was only 7.6%, demonstrating high tolerability and patient adherence. Most adverse reactions were rated mild to moderate (jaw tension, anxiety, dizziness, sleepiness, lack of appetite, nausea) and there were no unexpected MDMA-related adverse events within these trials. MDMA has been shown to be non-addictive and non-toxic at doses used in clinical research trials. Doses well above these have been shown to be potentially neurotoxic in some studies of poly-drug users.

MDMA exerts its efficacy through anxiolytic, prosocial effects which work to negate the avoidance and hyperarousal characteristic of PTSD known to inhibit the therapeutic process. Neurologically, patients with PTSD experience increased activity in the amygdala and decreased pre-frontal functioning. In contrast, MDMA decreases activity in the amygdala and increases blood-flow to prefrontal regions. This neurobiological state creates a fertile ground for therapeutic work by decreasing fear and enhancing a patient’s capacity for communication and self-compassion.

The advanced provision of MDMA-assisted therapy has been granted under the FDA’s ‘Expanded Access Scheme’ in the US and in Israel under the ‘Compassionate Access Scheme’. Australia would be following the international lead by making MDMA-assisted therapy available for at-risk patients.

The authorised provision of MDMA-assisted psychotherapy under Special Access Scheme Category B would include:

* Adherence to guidelines and protocols as specified by MAPS in the FDA approved Phase 3 treatment protocols
* Three active session doses of MDMA in separate in-clinic sessions of psychotherapy across 6-8 hours for each patient. A flexible dosing regimen was chosen to mimic proposed clinical practice and better adapt to risk benefit considerations

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| **Experimental Session** | **Initial Dose** | **Supplemental Dose\*** | **Min – Max Cumulative Dose:** |
| 1 | 80mg | 40mg | 80mg to 120 mg |
| 2 | 80 or 120\* mg | 40 mg or 60 mg | 80 mg to 180 mg |
| 3 | 80 or 120\* mg | 40 mg or 60 mg | 80 mg to 180 mg |
| **Total Cumulative Dose:** | | | 1. mg to 480 mg |

\* if initial dose well tolerated and with clinician judgement

* The provision of clinical support for this in the form of an appropriately trained psychiatrist, general practitioner, physician, psychologist, psychotherapist, counsellor, mental health social worker and /or nurse to conduct the psychotherapy in the preparatory, acute and integration sessions.
* Creation of the recommended clinical setting, including adherence to protocols for safety and security and the management of risk.
* Pre- and post-treatment clinical and psychological assessment to enable an evidence-based approach to reporting on outcomes. Including the report of any adverse or unexpected events to the TGA
* Provision of the medication as obtained directly from MAPS, thereby ensuring research-quality standards.
* Appropriate security measures for handling, safekeeping, and administration of a schedule 9 substance.
* Established support and collaboration with MAPS by providing data for inclusion in their study. Data similarly being gathered and processed for inclusion in any future local study.

Thank you for reviewing this application, I look forward to your response.   
  
Yours sincerely,

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