SOUTH AFRICAN SOCIETY OF PSYCHIATRISTS
POSITION STATEMENT

SASOP Position Statement

on the Use of Psychedelic & Empathogenic Agents for Mental Health Conditions

November 2022

A. Purpose

SASOP developed this Position Statement to provide information for psychiatrists about the potential utility of psychedelic substances for mental health conditions.

B. Key Messages

1. There is limited but emerging evidence that psychedelic substances combined with psychotherapeutic interventions may have therapeutic benefits in the treatment of a range of mental illnesses.
2. MDMA and psilocybin are the most well studied, and may show promise in highly selected populations when administered in closely supervised settings and with intensive support. Additional and larger randomised-control trials are needed to confirm initial promising results.
3. Current research confirms the presence of psychological support as an essential component of the psychedelic treatment model.
4. Further research is required to assess the efficacy, safety and effectiveness of psychedelic therapies to inform future potential use in psychiatric practice.
5. Clinical use of psychedelic substances should only occur under research trial conditions that include oversight by an institutional research ethics committee and careful monitoring and reporting of efficacy and safety outcomes.
6. SASOP concurs with the South African National Drug Master Plan (2019 – 2024) that calls for SAHPRA to periodically re-evaluate or re-assess the scheduling of substances based on the risk-access profile of the substance and that impediments to the availability and accessibility of controlled substances for medical and scientific purposes must be removed.
7. Psychiatrists have an ethical duty to follow a harm reduction approach that is evidence-based and complies with legal and professional practice guidelines when patients indicate that they are likely to seek access to unregulated psychedelic substance use in a non-research setting.

C. Definition & Scope

The scope of this position statement about the use of psychedelic substances and therapies for mental health conditions includes clinical practice and research settings and excludes settings where psychedelic substances are used recreationally or for religious or cultural purposes. Most recent research into psychedelic therapy has focused on methylenedioxymethamphetamine (MDMA), a chemical sometimes found in the drug ecstasy, and psilocybin, a compound in its natural form found in a number of species of psychedelic mushrooms (Reiff et al, 2020). These substances are the primary focus for this SASOP position statement, although it does cover use of other psychedelic substances in therapeutic use. This SASOP position statement excludes the use of ketamine, as SASOP developed a separate position statement on the use of ketamine.

- Psychedelic substances (also called psychedelic drugs or hallucinogens) are any of the so-called mind-expanding drugs that are able to induce states of altered perception and thoughts, frequently with heightened awareness of sensory input but with diminished control over what is being experienced.
- Psychedelic therapy refers to therapeutic practices involving psychedelic substances.
- Harm reduction in clinical practice refers to the clinical interventions that reduce the potential negative effects of substance use. Harm reduction occurs within a legal and regulatory context and is based on the ethical requirement that clinicians have a duty to reduce the risk of harm while respecting the patient's dignity and autonomy.

D. Background

Novel and effective therapeutic interventions are urgently needed to address the rising incidence and prevalence of psychiatric conditions globally (GBD 2019 Mental Disorders Collaborators, 2022). The increasing burden of mental illnesses, the barriers to accessing treatment, and the proportion of patients who fail to respond adequately to evidence-based interventions are some of the factors that emphasize the need to support innovation in mental healthcare (Wainberg et al, 2017). An increasing number of clinical trials evaluating psychedelic therapy have found promising results in a variety of psychiatric conditions, including treatment-resistant depression, end-of-life anxiety in terminal illnesses, substance use disorders, post-traumatic stress disorders, and anxiety disorders (Luoma et al, 2020). Internationally policy changes that support decriminalization and legalization have been made based on the emerging scientific evidence of the relative safety and effectiveness of psychedelic therapy (Belouin et al, 2022; Dos Santos et al, 2021).

Increasing public awareness and enthusiasm for psychedelic therapy and the lack of a clear legal and medical pathway to accessing psychedelic therapy, contributes to unregulated use of psychedelic substances (Pilecki et al, 2021). Individuals intending to use psychedelic substances for their mental health or self-exploration may approach clinicians to ask for advice or recommendations for referral to practitioners that offer unregulated psychedelic therapy. Any action that increases the chance a patient claims their use of a prohibited substance was because of the involvement of a licensed practitioner might result in a licensing board determining that the clinician was an integral part of the illegal experience under the guise of providing professional services (thereby violating duty of care and acting in an unprofessional or unethical manner). Due to the commitment to ethical and professional principles guiding patient care, clinicians may find themselves facing the dilemma of addressing the individual's unique needs (e.g. reducing potential harm) while respecting the professional and legal requirements of the profession and larger society (Gorman et al, 2021).

Medicine scheduling allows for different levels of regulatory control of substances. Psychedelic substances such as psilocybin, lysergic acid diethylamide (LSD), and MDMA are in the Schedule 1 of the United Nations Convention on Psychotropic Substances from 1971 which means that they are illegal under South African law. In the South

African setting The Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973) provide the mandate to the South African Health Products Regulatory Authority (SAHPRA) to regulate all health products.

Psychedelic substances such as psilocybin and MDMA are currently scheduled by SAHPRA as Schedule 7 indicating that they are "not recognized for medical use and have an extremely high potential for abuse or producing dependence with limited scientific purposes." This restrictive scheduling status means that access to these substances may only be obtained under special conditions and a Section 21 application may be submitted to SAHPRA to allow import.

South Africa's National Drug Master Plan (4th edition) for the period 2019 to 2024 states as one of its goals the increase in the availability of and access to controlled substances exclusively for medical and scientific purposes while preventing their diversion. The Plan calls on SAHPRA to periodically re-evaluate or re-assess the scheduling of substances based on the risk-access profile of the substance and that impediments to the availability and accessibility of controlled substances for medical and scientific purposes must be removed. The National Drug Master Plan also emphasizes that harm reduction interventions are evidence-based public health principles to support people who use drugs. Harm reduction interventions aim to reduce the current and future risks and potential harms related to drug use. Rather than ignoring or condemning harmful behavior, it seeks to work with the individual or community to minimize the harmful effects of specific behaviors.

E. SASOP Position

1. SASOP welcomes the emergence of safe, evidence-based treatment options to address the shortcomings of currently available treatment options for individuals with mental health disorders. SASOP has a duty to support the development of emerging evidence-based treatments and clinical trial research into promising therapeutic options, provided they are conducted with patient well- being and safety being paramount.
2. Until there is sufficient compelling clinical evidence, and systematic research to overcome the current limitations, SASOP would not, at this stage, endorse the widespread use of psychedelic-assisted therapy. The clinical use of psychedelic substances should only occur under research trial conditions that include oversight by an institutional research ethics committee and careful monitoring and reporting of efficacy and safety outcomes. Active research is encouraged to build on the current evidence-base.
3. Regulatory approval of psychedelic therapy should not pre-empt the adequate evidence-base of the treatment. In addition, prior to any regulatory approval or movement into use outside of research trials, there is need for appropriate treatment methodologies, adequate training by those delivering the treatment, and an ethical and legal framework that provides appropriate safeguards.
4. SASOP supports psychiatrists continuing to expand their knowledgebase through continuous medical education and to contribute within the framework of current research practice to help inform the future use of psychedelic therapy.
5. SASOP concurs with the South African National Drug Master Plan (2019 – 2024) that calls for SAHPRA to periodically re-evaluate or re-assess the scheduling of substances based on the risk-access profile of the substance and that impediments to the availability and accessibility of controlled substances for medical and scientific purposes must be removed. Given the inhomogeneity of different psychedelics' effects and safety and efficacy profiles, it is not appropriate to treat them the same. Specific research is required to determine each substance's therapeutic potential.

6. Psychiatrists are ethically bound by the principles of respecting patient autonomy, non-maleficence, and beneficence. SASOP concurs with the South African National Drug Master Plan (2019 – 2024) that emphasises a harm reduction approach that is evidence-based and complies with legal, professional practice, and ethical requirements. Clinicians should follow a harm reduction approach when patients indicate that they are likely to seek access to unregulated psychedelic substance use in a non-research setting.

F. References

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