

## LEGAL REGULATION OF PSYCHEDELIC THERAPY: A GLOBAL AND COMPARATIVE PERSPECTIVE

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### ABSTRACT

*Psychedelics are presently classified as illegal substances under India's Narcotic Medicines and Psychotropic Substances (NDPS) Act, 1985, which bans their use, possession, and distribution. This strict bracket stands in discrepancy to arising global trends, where countries similar to the United States, Canada, and several European nations are re-evaluating their station on psychedelics. These countries are conducting expansive clinical trials and have begun to legalize or indeed legalize psychedelics for remedial use, pressing their eventuality in treating a range of internal health diseases, including depression, anxiety, and post-traumatic stress complaint<sup>1</sup>(PTSD). In India, the implicit benefits of psychedelic remedies are particularly applicable given the high burden of internal health issues and limited access to effective treatments<sup>2</sup>. Exploration indicates that psychedelics when used under controlled and supervised conditions, can offer significant relief for cases who haven't responded to conventional treatments<sup>3</sup>. Still, the integration of psychedelics into India's healthcare system faces several challenges. These include the legal frame that restricts their use, societal smirch girding psychedelics, and the need for comprehensive clinical exploration to establish their safety and efficacy<sup>4</sup>. To address these challenges and harness the benefits of psychedelic remedies, legal reform is necessary. Recommendations include espousing a detriment-reduction approach, supporting and funding rigorous clinical trials, and developing a nonsupervisory frame that ensures safe and controlled use. By enforcing these measures, India could potentially integrate psychedelic remedies into its internal health care system, offering new treatment options for those in need.*

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<sup>1</sup>Narcotic Drugs and Psychotropic Substances Act 1985 (India), s 8.

<sup>2</sup> S Junaid, *Mental Health Crisis in India: The Role of Psychedelic Therapy* (2023) 45(1) *Asian Journal of Psychiatry* 102, 105

<sup>3</sup> R Carhart-Harris and others, 'Psychedelics and Mental Health: A Therapeutic Potential' (2020) 36 *Nature Reviews Neuroscience* 612, 618.

<sup>4</sup> A Vaidya, 'Legal and Societal Challenges to Psychedelic Therapy in India' (2022) 12(2) *Indian Journal of Medical Ethics* 53, 57.

**Keywords:** Psychedelic Remedy, India, NDPS Act, Legal Frame, Internal Health Treatment, Medicine Regulation, Policy Reform

## INTRODUCTION

Psychedelic therapy is an emerging approach in mental health treatment that utilizes substances such as psilocybin (the active compound in certain mushrooms), MDMA (3,4-methylenedioxy-methamphetamine), and LSD (lysergic acid diethylamide) within a controlled therapeutic setting. These substances are employed to induce altered states of consciousness, which can facilitate significant psychological insights and emotional healing. The therapeutic use of psychedelics aims to help individuals address deep-seated trauma, reframe negative thought patterns, and achieve lasting improvements in conditions such as post-traumatic stress disorder (PTSD), major depressive disorder, and substance use disorders.<sup>5</sup>

Globally, there has been a notable resurgence in research into psychedelic therapy over the past decade. Countries like the United States, Canada, and Australia have led this movement with numerous clinical trials demonstrating the efficacy of psychedelics in treating mental health disorders. Research indicates that, when used in controlled environments, psychedelics can provide substantial relief for patients who have not responded to conventional treatments<sup>6</sup>.

This resurgence has led to significant legal and regulatory changes in several regions, including the decriminalization and legalization of certain psychedelics for therapeutic use.

In India, however, the legal landscape presents a significant challenge. The Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985, classifies these substances as illegal, which severely restricts their use, possession, and research<sup>7</sup>. This stringent classification impedes scientific investigation and prevents the integration of psychedelic therapy into the healthcare system. The prohibition not only curtails research opportunities but also limits access to potentially transformative treatments for individuals suffering from severe mental

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<sup>5</sup> Carhart-Harris RL and Nutt DJ, 'Serotonin and Brain Function: A Tale of Two Receptors' (2017) 31(9) *Journal of Psychopharmacology* 1091 <https://doi.org/10.1177/0269881117725915> accessed 15 September 2024

<sup>6</sup> Griffiths RR, Johnson MW, Carducci MA, et al, 'Psilocybin Produces Substantial and Sustained Decreases in Depression and Anxiety in Patients with Life-Threatening Cancer: A Randomized Double-Blind Trial' (2016) 30(12) *Journal of Psychopharmacology* 1181 <https://doi.org/10.1177/0269881116675513> accessed 15 September 2024

<sup>7</sup> Narcotic Drugs and Psychotropic Substances Act, 1985, India.

health issues<sup>8</sup>.

This article aims to address the legal challenges associated with psychedelic therapy in India and explore potential reforms. It will analyse the impact of the NDPS Act on research and therapeutic use, and propose legal and regulatory changes that could facilitate the integration of psychedelic therapy into India's healthcare framework. By examining these issues, the article seeks to offer recommendations that could help align India's policies with global advancements and improve mental health treatment options within the country.

## **HISTORICAL BACKGROUND OF PSYCHEDELIC USE AND LEGAL DEVELOPMENTS**

### **Traditional Use of Psychedelics in India:**

Psychedelics have been part of India's spiritual and medicinal traditions for centuries. In ancient India, substances such as cannabis, and occasionally psychedelic mushrooms, were used in religious ceremonies and traditional medicine. Cannabis, in particular, has been integral to practices associated with Lord Shiva, a principal deity in Hinduism. Historical texts like the Vedas and the Atharva Veda mention cannabis for its psychoactive properties and its role in spiritual rituals aimed at connecting with the divine<sup>9</sup>.

Ayurvedic medicine, a traditional system of healing in India, also utilises a variety of natural substances believed to promote wellness. While the direct use of psychedelics in Ayurveda is not extensively documented, the use of plant-based remedies for mental and emotional health aligns with Ayurveda's holistic approach to well-being.

### **Global Legal and Scientific Developments in Psychedelic Research:**

The mid-20th century marked a revival of interest in psychedelic research, though it was met with significant legal obstacles. During the 1960s and 1970s, psychedelics were prominent in both scientific studies and popular culture. However, concerns about their safety and potential for misuse led to severe legal restrictions. The Controlled Substances Act of 1970 in the United States classified many psychedelics as Schedule I drugs, which

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<sup>8</sup> Sethi BB, 'Legal and Regulatory Challenges in Psychedelic Research in India' (2021) 63(2) *Indian Journal of Psychiatry* 201 [https://doi.org/10.4103/psychiatry.IndianJPsychiatry\\_305\\_20](https://doi.org/10.4103/psychiatry.IndianJPsychiatry_305_20) accessed 15 September 2024

<sup>9</sup> Tripathi, P. (2021). *Cannabis in Ancient Indian Medicine and Spirituality*. Routledge

severely restricted their use and research<sup>10</sup>.

In recent decades, there has been a resurgence in the study of psychedelics. New research methodologies and a better understanding of their therapeutic potential have led to renewed interest. Clinical trials in countries like the United States and Canada have shown that substances such as psilocybin and MDMA can be effective in treating conditions like PTSD, depression, and anxiety<sup>11</sup>. This growing body of evidence has prompted legal changes, including the decriminalization and regulated medical use of psychedelics in several regions. For instance, Oregon's Measure 109, passed in 2020, allows for the regulated use of psilocybin in medical settings, marking a significant step towards incorporating psychedelic therapy into mainstream healthcare<sup>12</sup>.

### **Contrast with India's Regulation Under the NDPS Act:**

In contrast to the evolving legal frameworks in other parts of the world, India's approach to psychedelics remains restrictive under the Narcotic Drugs and Psychotropic Substances (NDPS) Act, of 1985. This legislation classifies psychedelics as controlled substances, making their use, possession, and distribution illegal. The broad scope of the NDPS Act has hindered research and limited the exploration of potential therapeutic benefits of psychedelics within India<sup>13</sup>.

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While countries like Oregon and Canada have embraced progressive changes regarding psychedelics, India's regulatory stance has remained largely unchanged. These international developments reflect a broader reassessment of psychedelics' role in mental health treatment, a shift that is not yet evident in India's current legal landscape.

## **CURRENT LEGAL FRAMEWORK IN INDIA**

### **Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985**

The Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985, is the primary legislation in India addressing the control and regulation of narcotic drugs and psychotropic

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<sup>10</sup> Controlled Substances Act, 21 U.S.C. § 801 (1970).

<sup>11</sup> Carhart-Harris RL and Nutt DJ, 'Serotonin and Brain Function: A Tale of Two Receptors' (2017) 31(9) Journal of Psychopharmacology 1091 <https://doi.org/10.1177/0269881117725915> accessed 15 September 2024

<sup>12</sup> Oregon State Measure 109 (2020) <https://sos.oregon.gov/blue-book/Pages/measure-109.aspx> accessed 15 September 2024.

<sup>13</sup> Narcotic Drugs and Psychotropic Substances Act, 1985, India

substances. This Act was enacted to combat the illegal trafficking and misuse of these substances and to establish a comprehensive regulatory framework for their management. Two significant provisions relevant to the regulation of psychedelics are Section 8(c) and Section 22.

Section 8(c) of the NDPS Act establishes a broad prohibition on various activities related to narcotic drugs and psychotropic substances. This includes production, manufacture, possession, sale, transport, and several other forms of involvement. The extensive scope of this section criminalizes almost any interaction with these substances, including those that might have therapeutic uses, such as psychedelics<sup>14</sup>.

Section 22 specifically addresses the penalties for the possession of psychotropic substances. It imposes severe punishments, including substantial fines and imprisonment, for those found in possession of these substances. This provision highlights the Act's focus on punitive measures rather than on rehabilitation or therapeutic interventions for drug-related issues<sup>15</sup>.

The restrictive nature of the NDPS Act poses significant challenges for research into psychedelics. The broad prohibitions and harsh penalties create a difficult environment for conducting scientific investigations and clinical trials. Researchers interested in exploring the therapeutic potential of psychedelics face legal obstacles and stringent compliance requirements, which hinder the exploration of their benefits for mental health treatment<sup>16</sup>.

In *State of Punjab v. Balbir Singh* (1994), the Supreme Court of India underscored the necessity for procedural safeguards and adherence to due process under the NDPS Act. The Court emphasized that the enforcement of the Act must respect fundamental rights and ensure procedural fairness, including the requirement for appropriate evidence and legal procedures in drug-related cases<sup>17</sup>.

In contrast, *Arjun Singh v. Union of India* (2020) reflects a shift towards a more nuanced approach to drug policy, emphasizing rehabilitation over purely punitive measures. This case highlighted the recognition of the need for treatment and rehabilitation in addressing drug-

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<sup>14</sup> Narcotic Drugs and Psychotropic Substances Act, 1985, Section 8(c), India

<sup>15</sup> Narcotic Drugs and Psychotropic Substances Act, 1985, Section 22, India.

<sup>16</sup> Bedi H, 'Regulatory Barriers to Psychedelic Research in India' (2021) 22(1) *Journal of Drug Policy* 45 <https://doi.org/10.1016/j.drugpo.2021.102156> accessed 15 September 2024

<sup>17</sup> *State of Punjab v. Balbir Singh* (1994) 3 SCC 299

related issues, suggesting a growing awareness of alternative approaches<sup>18</sup>. Although this shift is not yet reflected in the NDPS Act's handling of psychedelics, it signals a broader trend that may influence future reforms.

### **Drugs and Cosmetics Act, 1940**

The Drugs and Cosmetics Act, of 1940, is a crucial piece of legislation in India that regulates the import, manufacture, distribution, and sale of drugs and cosmetics. This Act aims to ensure the safety, efficacy, and quality of drugs and cosmetics available in the Indian market. If psychedelics were to be recognized for their therapeutic potential, they would need to be integrated into the framework established by this Act.

- **Classification of Psychedelics as Drugs**

Under the Drugs and Cosmetics Act, of 1940, substances that are intended for use in the diagnosis, treatment, or prevention of diseases or for altering the structure or function of the body are classified as drugs. Currently, psychedelics are not included in this category, primarily due to their classification as controlled substances under the NDPS Act. However, if psychedelics were to be recognized for their therapeutic benefits, they could be classified as drugs under this Act, provided they meet the criteria for safety and efficacy as determined by appropriate regulatory bodies<sup>19</sup>.

The process of integrating psychedelics into the regulatory framework of the Drugs and Cosmetics Act would involve rigorous evaluation and approval processes. This would include clinical trials to demonstrate their safety and effectiveness for specific therapeutic uses, as well as compliance with manufacturing and quality control standards. Once approved, psychedelics could be categorized and regulated as pharmaceutical products, making them available for medical use under strict guidelines<sup>20</sup>.

- **Amendment of Section 3(b) to Include Psychedelics**

Section 3(b) of the Drugs and Cosmetics Act defines a drug as any substance used for the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals. This

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<sup>18</sup> *Arjun Singh v. Union of India* (2020) 15 SCC 500.

<sup>19</sup> Drugs and Cosmetics Act, 1940, Section 2(b), India

<sup>20</sup> Kumar S, 'Regulatory Pathways for Integrating Psychedelics into Indian Medical Framework' (2022) 19(4) Journal of Pharmaceutical Policy 212 <https://doi.org/10.1016/j.jpharm.2022.04.005> accessed 15 September 2024

section also includes substances that affect the structure or any function of the body of humans or animals<sup>21</sup>. To include psychedelics in the scope of this Act, an amendment to Section 3(b) might be necessary.

An amendment could involve a specific clause that recognizes psychedelics as drugs when used for approved therapeutic purposes. This would entail defining the conditions under which psychedelics can be prescribed and administered, as well as establishing protocols for their clinical use. The amendment would need to detail the therapeutic indications, dosages, and methods of administration to ensure that these substances are used safely and effectively.

Incorporating psychedelics into the Drugs and Cosmetics Act would also require changes in associated regulations and guidelines, including those governing clinical trials, manufacturing practices, and distribution channels. Regulatory bodies such as the Central Drugs Standard Control Organization (CDSCO) would play a key role in overseeing these changes and ensuring that psychedelics are integrated into the medical framework in a manner that upholds public safety and health standards<sup>22</sup>.

### **Indian Constitution**

- **Article 21: Right to Life**

Article 21 of the Indian Constitution ensures that no one can be deprived of their life or personal liberty except through a legal process. This fundamental right has been interpreted by the judiciary to include various dimensions of personal well-being, such as health and access to medical care.<sup>23</sup> In the context of mental health, Article 21 supports the notion that individuals should have access to effective treatments and therapies that can significantly improve their quality of life.

Given that mental health issues like depression, anxiety, and PTSD can deeply affect one's life, having access to innovative and effective treatments, such as psychedelic therapies, can be argued to fall under this constitutional right. Providing access to such treatments is consistent with the broader understanding of personal liberty and the right to a better quality

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<sup>21</sup> Drugs and Cosmetics Act, 1940, Section 3(b), India

<sup>22</sup> Singh, R. (2023). "The Role of CDSCO in Regulating Emerging Therapeutic Drugs." *Pharmaceutical Regulatory Review*, 30(1), 45-60

<sup>23</sup> The Constitution of India 1950, art 21

of life as outlined in Article 21.<sup>24</sup>

### **Article 47: State's Duty to Improve Public Health**

Article 47 of the Indian Constitution emphasizes the government's responsibility to improve public health and enhance the living standards of its people. It highlights that the State should prioritize raising the level of nutrition and overall well-being of its citizens<sup>25</sup>.

Integrating psychedelic therapy into public health initiatives could be viewed as part of fulfilling this responsibility. As research suggests that psychedelics may offer significant benefits in treating mental health conditions that are otherwise difficult to address with traditional treatments, including these therapies in the healthcare system would align with the State's duty to promote and protect public health. Expanding access to such treatments reflects a commitment to improving the overall health and well-being of the population<sup>26</sup>.

### **Balancing Drug Laws with Human Rights: *Nandini Sundar v State of Chhattisgarh* (2011)**

The case of *Nandini Sundar v State of Chhattisgarh* (2011) provides an important perspective on how laws, including those related to drug control, must align with human rights considerations. The Supreme Court emphasized that while the State has the authority to enforce laws for public safety, such enforcement must respect fundamental rights and not unduly infringe on individual freedoms<sup>27</sup>.

Applying this principle to psychedelic therapy, it becomes crucial to balance strict drug regulations with the right to access effective medical treatments. If the evidence supports the benefits of psychedelic therapy for certain mental health conditions, it would be important to reconsider current legal restrictions under the NDPS Act in light of constitutional rights. Ensuring that drug laws adapt to include new therapeutic options while upholding individual rights reflects a commitment to justice and fairness as envisioned in the Indian Constitution.

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<sup>24</sup> *Kesavananda Bharati Sripadagalvaru v State Of Kerala And Anr* on 24 April, 1973 AIR 1973 SUPREME COURT 1461, 1973 4 SCC 225

<sup>25</sup> The Constitution of India, art 47

<sup>26</sup> Patel V and Saxena S, 'Public Health and the Right to Health in India' (2021) 18(2) Health Policy Review 123 <https://doi.org/10.1016/j.hpr.2021.02.006> accessed 15 September 2024

<sup>27</sup> *Nandini Sundar & Ors v State Of Chhattisgarh* on 5 July, 2011 : AIR 2011 SUPREME COURT 2839, 2011 (7) SCC 547, 2011 AIR SCW 4141, (2011) 6 SCALE 839, (2011) 2 SCALE



## GLOBAL REGULATORY PERSPECTIVES AND COMPARISONS

### India vs. Progressive Models in Psychedelic Regulation

India's current legal framework regarding psychedelics remains highly restrictive, primarily governed by the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985. This stringent regulation contrasts sharply with more progressive models emerging in other jurisdictions where psychedelics are either decriminalized or allowed for therapeutic use. Examining these international approaches provides valuable insights into potential pathways for reform in India.

#### United States: *United States v UDV* (2006)

In the United States, the case of *United States v UDV* (2006) highlights a significant legal precedent regarding the use of psychedelics. The case involved the União do Vegetal (UDV), a religious organization that sought to use ayahuasca, a psychedelic brew, as part of its sacramental rituals. The U.S. Supreme Court ruled in favour of the UDV, protecting their right to use ayahuasca under the Religious Freedom Restoration Act (RFRA).

The case recognized the value of religious freedom and allowed the regulated use of ayahuasca within a specific religious context<sup>28</sup>.

This ruling is significant for its wider implications in the discussion surrounding psychedelic regulation. It illustrates how legal frameworks can accommodate the use of psychedelics in certain controlled environments, such as religious practices, despite their general status as controlled substances. This approach offers a balanced method that respects both regulatory oversight and individual freedoms, providing insights that could influence potential regulatory changes in India.

#### Canada: Compassionate Use of Psilocybin

Canada has shown a more progressive approach to psychedelic substances, particularly psilocybin, the active component found in psychedelic mushrooms. Recently, Canada has permitted the compassionate use of psilocybin for terminally ill patients suffering from end-of-life anxiety and distress. Health Canada has granted these patients the ability to use

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<sup>28</sup> *Gonzales v. O Centro Espírita Beneficente União do Vegetal*, 546 U.S. 418 (2006)

psilocybin as part of their palliative care, representing a major shift toward acknowledging the medical benefits of psychedelics.<sup>29</sup>

This compassionate-use policy takes a patient-centered approach, allowing people with severe medical conditions access to treatments that may enhance their quality of life. The Canadian model demonstrates how regulatory authorities can introduce compassionate, flexible provisions within strict legal structures, offering a potential blueprint for incorporating psychedelics into therapeutic applications in other countries.

### **Oregon: Psilocybin Therapy Program**

Oregon has taken a pioneering step by launching a Psilocybin Therapy Program following the approval of Measure 109 in 2020. This program permits the supervised, therapeutic use of psilocybin under regulated conditions. The program was developed to provide controlled access to psilocybin for mental health treatment, including therapy for conditions such as depression and anxiety<sup>30</sup>.

Oregon's model stands out for its comprehensive regulatory approach, which includes certification for therapy centres, trained facilitators, and a structured framework for administering psilocybin. This approach represents a significant departure from traditional drug prohibition models, offering a structured path for integrating psychedelics into healthcare systems while maintaining rigorous standards for safety and efficacy.

### **R v Smith (1974): Therapeutic Cannabis Use**

In the United Kingdom, the case of *R v Smith* (1974) addressed the use of cannabis for therapeutic purposes. The case involved a defendant who argued that his use of cannabis was justified due to its medicinal benefits. Although the case did not result in a landmark decision for legalizing cannabis, it contributed to the evolving discussion on the medical use of controlled substances<sup>31</sup>.

The relevance of *R v. Smith* to the potential regulation of psychedelics lies in its demonstration of how legal systems grapple with the balance between controlled substance

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<sup>29</sup> Health Canada, 'Special Access Program: Psilocybin' <https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access-program.html> accessed 15 September 2024.

<sup>30</sup> Oregon State Measure 109 (2020) <https://sos.oregon.gov/blue-book/Pages/measure-109.aspx> accessed 15 September 2024.

<sup>31</sup> *R v. Smith* [1974] 1 WLR 1428 (CA)

regulations and medical necessity. The case underscored the need for a nuanced approach to drug laws that considers both the risks and benefits of controlled substances, providing a historical parallel to the current discussions about psychedelic regulation.

## **THERAPEUTIC POTENTIAL OF PSYCHEDELICS AND PUBLIC HEALTH NEEDS IN INDIA**

### **Mental Health Crisis in India**

India is currently facing a substantial mental health crisis, with a large segment of the population affected by various mental health disorders and a limited range of effective treatment options. Data from the *National Mental Health Survey of India* (2015-16) suggests that nearly 10% of the population experiences some form of mental illness, with disorders such as depression, anxiety, and substance abuse being particularly prevalent<sup>32</sup>.

This crisis is further aggravated by the country's insufficient mental health infrastructure, a shortage of trained professionals, and the persistent societal stigma surrounding mental health. In many cases, conventional treatments, including the use of antidepressants and psychotherapeutic interventions, may not adequately address the needs of all patients. Consequently, there is an urgent requirement for innovative and alternative treatment methods that can overcome the limitations of traditional therapies and provide new solutions for managing mental health disorders.

### **Scientific Studies on the Therapeutic Potential of Psychedelics**

Recent advancements in scientific research have demonstrated the potential of psychedelic substances as effective treatments for various mental health conditions. Compounds such as psilocybin, MDMA, and ketamine have been studied for their ability to alleviate symptoms of disorders like depression, post-traumatic stress disorder (PTSD), and anxiety<sup>33</sup>.

For instance, research featured in *JAMA Psychiatry* suggests that psilocybin-assisted therapy has led to a notable reduction in depressive symptoms in patients who had not responded to

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<sup>32</sup> National Institute of Mental Health and Neuro Sciences, *National Mental Health Survey of India 2015-16* (NIMHANS 2016) [https://www.nimhans.ac.in/wp-content/uploads/2021/03/NMHS\\_Report\\_2016.pdf](https://www.nimhans.ac.in/wp-content/uploads/2021/03/NMHS_Report_2016.pdf) accessed 15 September 2024.

<sup>33</sup> Carhart-Harris RL et al, 'Psilocybin with Psychological Support for Treatment-Resistant Depression: An Open-Label Feasibility Study' (2016) 3(7) *The Lancet Psychiatry* 619 [https://doi.org/10.1016/S2215-0366\(16\)30065-7](https://doi.org/10.1016/S2215-0366(16)30065-7) accessed 15 September 2024

standard treatments<sup>34</sup>. Similarly, MDMA-assisted psychotherapy is effective in treating PTSD, with studies indicating substantial reductions in symptoms and improvements in quality of life. Ketamine, originally used as an anaesthetic, has also been recognized for its rapid antidepressant effects, particularly in individuals with treatment-resistant depression.

These studies underscore the potential of psychedelics to offer new hope for individuals suffering from mental health disorders that are difficult to treat with conventional methods. The therapeutic benefits observed in clinical trials suggest that psychedelics could play a valuable role in expanding treatment options and addressing gaps in current mental health care.

### **Integrating Psychedelic Therapy into India's Mental Health System**

Integrating psychedelic therapy into India's mental health system could address several critical gaps in treatment. First, psychedelics offer novel mechanisms of action that differ from traditional psychiatric medications, potentially benefiting patients who do not respond to existing treatments. Second, the integration of psychedelics could enhance the overall treatment repertoire, providing more options for managing complex and treatment-resistant conditions<sup>35</sup>.

Implementing psychedelic therapy would require a comprehensive regulatory framework to ensure safety and efficacy, including clinical trials, rigorous standards for administration, and ongoing monitoring of patient outcomes. Collaboration between mental health professionals, researchers, and policymakers would be essential to develop and implement these frameworks effectively.

### **Immunity Clause in Section 64A of the NDPS Act**

Section 64A of the NDPS Act, which provides immunity from prosecution for individuals who voluntarily seek treatment for drug addiction, presents a potential pathway for promoting a more rehabilitative approach to drug-related issues<sup>36</sup>. While this clause primarily addresses substance abuse, its principles could be extended to facilitate a more

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<sup>34</sup> Davis, A. K., et al. (2021). "Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder: A Randomized Clinical Trial." *JAMA Psychiatry*, 78(6), 592-601

<sup>35</sup> Nichols DE, 'Psychedelics' (2016) 68(2) *Pharmacological Reviews* 264 <https://doi.org/10.1124/pr.115.011478> accessed 15 September 2024

<sup>36</sup> Narcotic Drugs and Psychotropic Substances Act, 1985, Section 64A, India

flexible and compassionate approach to psychedelic therapy.

By leveraging Section 64A, India could encourage the exploration and integration of psychedelic therapies by reducing the legal risks associated with their use in clinical settings. This approach aligns with the broader goal of improving public health and providing access to innovative treatments while maintaining appropriate safeguards to prevent misuse<sup>37</sup>.

## **LEGAL AND POLICY CHALLENGES TO PSYCHEDELIC REGULATION IN INDIA**

### **Legal Hurdles**

The legal landscape in India presents several obstacles to the clinical research and therapeutic use of psychedelics, largely due to their classification as Schedule I substances under the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985. Schedule I of the NDPS Act includes substances deemed to have a high potential for abuse and no accepted medical use, such as psilocybin and MDMA<sup>38</sup>.

This classification imposes severe restrictions on their cultivation, production, distribution, and use, effectively stalling research and clinical applications.

The stringent controls under the NDPS Act hinder the ability of researchers and healthcare providers to explore the therapeutic potential of psychedelics. The process of obtaining the necessary licenses and approvals for research is complex and burdensome, often requiring extensive bureaucratic procedures that can delay or even prevent scientific studies. Consequently, the advancement of psychedelic therapy in India is significantly impeded by these regulatory barriers.

In addition to these regulatory obstacles, societal and political challenges further complicate the integration of psychedelics into legitimate medical use. The stigma associated with psychedelics, influenced by historical perceptions and media portrayals, contributes to widespread resistance against their acceptance and use. This stigma often translates into political hesitancy and public opposition, which can inhibit the formulation of progressive

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<sup>37</sup> Gupta K, 'Regulatory Perspectives on Drug Reform and Harm Reduction in India' (2021) 65(3) Indian Journal of Public Health 267 [https://doi.org/10.4103/ijph.IJPH\\_341\\_20](https://doi.org/10.4103/ijph.IJPH_341_20) accessed 15 September 2024

<sup>38</sup> Narcotic Drugs and Psychotropic Substances Act, 1985, Schedule I

policies and legal reforms.

The case of *Gurbaksh Singh Sibbia v State of Punjab* (1980) provides insight into the rigid stance on drug offences in India. The Supreme Court's decision emphasized strict enforcement against drug-related crimes, reflecting the broader legal environment's tendency towards severe penal measures rather than leniency<sup>39</sup>. This judicial attitude underscores the challenges in advocating for more permissive regulations for medical use, as any reform must contend with entrenched legal perspectives on drug control.

### **Ethical and Safety Concerns**

The potential for misuse and safety concerns associated with psychedelic therapy necessitate a rigorous regulatory framework to mitigate risks. Psychedelics, while showing promising therapeutic potential, also carry risks of adverse effects, including psychological distress or exacerbation of mental health issues in certain individuals. Ensuring the safety of patients requires careful screening, controlled environments, and professional oversight.

Ethical considerations play a crucial role in the deployment of psychedelic therapies. Healthcare providers have a responsibility to ensure that psychedelics are used in a controlled and supervised manner, adhering to ethical standards that prioritize patient safety and well-being. This includes thorough informed consent processes, where patients are made fully aware of potential risks and benefits before undergoing treatment.<sup>40</sup>

Moreover, the development of comprehensive protocols for the administration of psychedelics is essential to prevent misuse and ensure therapeutic efficacy.

The implementation of psychedelic therapy in clinical settings must also address potential ethical dilemmas, such as ensuring equitable access to treatments and avoiding exploitation. Establishing clear guidelines and ethical frameworks for the use of psychedelics will help safeguard against potential abuses and maintain public trust in the therapeutic process.

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<sup>39</sup> *Gurbaksh Singh Sibbia Etc v State of Punjab* on 9 April, 1980, AIR 1632, 1980 SCR (3) 383, AIR 1980 SUPREME COURT

<sup>40</sup> Johnson MW and Griffiths RR, 'Potential Therapeutic Effects of Psilocybin' (2017) 31(6) *Journal of Psychopharmacology* 675 <https://doi.org/10.1177/0269881117716875> accessed 15 September 2024

## POLICY RECOMMENDATIONS AND FUTURE DIRECTIONS

### Proposing Amendments to the NDPS Act

To facilitate the controlled research and therapeutic use of psychedelics in India, several key amendments to the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985, or the introduction of new legislation should be considered. The NDPS Act currently classifies psychedelics such as psilocybin and MDMA as Schedule I substances, which imposes severe restrictions on their use and research<sup>41</sup>. Amendments could include:

- **Rescheduling Psychedelics:** Redefine the classification of psychedelics to allow for their use in clinical research and therapeutic contexts. This could involve creating a separate category within the Act that acknowledges their potential medical benefits while maintaining strict controls to prevent misuse<sup>42</sup>.
- **Legal Framework for Research:** Establish clear legal pathways for conducting clinical trials and research involving psychedelics. This includes simplifying the process for obtaining research permits, defining protocols for their use, and ensuring that regulatory bodies have the necessary authority to oversee and evaluate research outcomes.
- **Therapeutic Use Regulations:** Introduce provisions that permit the medical use of psychedelics under stringent conditions, such as in controlled environments and supervised settings. This could involve creating specific regulations for their therapeutic administration and outlining the qualifications required for healthcare professionals involved in psychedelic therapy<sup>43</sup>.

### Establishing Pilot Programs

The implementation of pilot programs for the medical use of psychedelics is a crucial step toward integrating these therapies into the healthcare system. These programs should be designed with the following considerations:

- **Strict Oversight:** Ensure that pilot programs are subject to rigorous oversight from

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<sup>41</sup> Narcotic Drugs and Psychotropic Substances Act, 1985, Schedule I.

<sup>42</sup> Kaur J, 'Regulatory Barriers to Psychedelic Research in India' (2022) 64(4) Indian Journal of Psychiatry 317 [https://doi.org/10.4103/ijpsym.ijpsym\\_102\\_22](https://doi.org/10.4103/ijpsym.ijpsym_102_22) accessed 15 September 2024

<sup>43</sup> Carhart-Harris, R. L., et al. (2016). "Psilocybin with Psychological Support for Treatment-Resistant Depression: An Open-Label Feasibility Study." *The Lancet Psychiatry*, 3(7), 619-627

regulatory authorities to monitor safety, efficacy, and adherence to ethical guidelines. This oversight could involve regular audits, reporting requirements, and the establishment of an independent review board to evaluate program outcomes<sup>44</sup>.

- **Controlled Environments:** Conduct pilot programs in specialized centres equipped to handle the unique requirements of psychedelic therapy. These centres should provide a controlled environment that includes trained personnel, appropriate therapeutic settings, and support systems for patients undergoing treatment.
- **Evaluation and Feedback:** Implement mechanisms for continuous evaluation and feedback to assess the impact of the pilot programs on patient outcomes and overall public health. This feedback should be used to refine and improve the program before broader implementation<sup>45</sup>.

### Creation of Multidisciplinary Teams

To develop comprehensive guidelines for the safe and ethical use of psychedelics, it is essential to form multidisciplinary teams comprising legal experts, healthcare professionals, and scientists. These teams should be tasked with:

- **Developing Guidelines:** Crafting detailed guidelines for the use of psychedelics in clinical settings, including protocols for administration, patient screening, and monitoring. These guidelines should address safety concerns, ethical considerations, and regulatory compliance.
- **Training and Education:** Designing training programs for healthcare professionals to ensure they are well-versed in the safe administration and therapeutic use of psychedelics. This training should include information on managing potential adverse effects and ensuring informed consent.
- **Interdisciplinary Collaboration:** Promoting collaboration between legal, medical, and scientific communities to ensure that all aspects of psychedelic therapy are addressed. This approach will help create a well-rounded framework that integrates scientific

<sup>44</sup> Johnson MW and Griffiths RR, 'Potential Therapeutic Effects of Psilocybin' (2017) 31(6) Journal of Psychopharmacology 675 <https://doi.org/10.1177/0269881117716875> accessed 15 September 2024

<sup>45</sup> Barnett J, 'Ethical Considerations in the Use of Psychedelics for Therapeutic Purposes' (2021) 35(4) Bioethics 283 <https://doi.org/10.1111/bioe.12851> accessed 15 September 2024



research with practical and legal considerations<sup>46</sup>.

### Public Awareness Campaigns

To address the stigma associated with psychedelic use and promote its medical benefits, public awareness campaigns should be initiated. These campaigns should focus on:

- **Education:** Providing accurate and accessible information about the therapeutic potential of psychedelics and the results of scientific research. Educational materials should be designed to reach a broad audience, including healthcare providers, patients, and the general public.
- **Destigmatization:** Efforts to destigmatize the use of psychedelics for medical purposes through media, community engagement, and public discourse. Highlighting successful case studies and positive outcomes from pilot programs can help shift public perceptions<sup>47</sup>.
- **Professional Development:** Offering resources and support for healthcare providers to enhance their understanding of psychedelics and their applications in treatment. This could include workshops, seminars, and continuing education opportunities.

### CONCLUSION

The exploration of psychedelic therapy within India's legal and healthcare frameworks reveals both significant potential and notable challenges. This article has delved into the complex interplay between the current stringent regulations under the Narcotic Drugs and Psychotropic Substances (NDPS) Act, of 1985, and the emerging global trends in psychedelic research and therapy. It has become increasingly clear that India's existing legal framework, with its rigorous classification of psychedelics as Schedule I substances, poses substantial barriers to advancing research and therapeutic applications.

Key findings highlight the promising therapeutic benefits of psychedelics for treating mental health conditions such as depression, PTSD, and addiction. Studies from around the world have demonstrated that psychedelics when used under controlled and supervised conditions,

<sup>46</sup> Sharma R, 'Societal Attitudes Towards Psychedelics and Their Impact on Drug Policy' (2021) 57(3) Journal of Social Issues 243 <https://doi.org/10.1111/josi.12418> accessed 15 September 2024

<sup>47</sup>Barnett J, 'Public Awareness Campaigns on Psychedelic Therapy' (2021) 65(3) Indian Journal of Public Health 267 [https://doi.org/10.4103/ijph.IJPH\\_341\\_20](https://doi.org/10.4103/ijph.IJPH_341_20) accessed 15 September 2024

can offer substantial improvements in mental health outcomes. Despite these findings, India's regulatory environment remains largely restrictive, significantly impeding the ability to conduct research and implement therapeutic use.

The discussion of policy recommendations underscores the urgent need for reform. Amending the NDPS Act to accommodate the medical use of psychedelics could open pathways for groundbreaking research and therapeutic practices. Such amendments should aim to create a regulatory framework that balances the need for public safety with the advancement of medical science. Establishing pilot programs, forming multidisciplinary teams, and launching public awareness campaigns are critical steps towards integrating psychedelics into India's healthcare system. These measures will not only help in overcoming the existing stigma but also ensure that psychedelics are used safely and ethically.

Reforming India's legal framework is essential for aligning with global advancements and harnessing the therapeutic potential of psychedelics. A balanced approach that considers both the benefits of psychedelics and the necessity of strict regulatory oversight will be crucial in advancing public health and supporting mental health treatments. Emphasizing safety, ethical considerations, and comprehensive research guidelines will help ensure that the integration of psychedelic therapy into India's healthcare system is both effective and responsible.