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Global Practice Guides

Psychedelic Medicines

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Mackrell.Solicitors

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INTRODUCTION

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Mackrell.Solicitors is an award-winning, full-service law firm, which has provided high-quality legal advice and services since 1845. As a founder of Mackrell International, the 35-year-old global network comprising 90 firms across 60 countries, Mackrell.Solicitors can offer immediate international legal advice and assistance in any jurisdiction worldwide from its London headquarters and Birmingham office. The UK's first dedicated psychoactive medicines legal team was set up by the firm five years ago to provide regulatory advice and services for the psychedelic medicines, medicinal cannabis and cannabinoid industries. The team has market-leading sector knowledge and is at the cutting edge of the current EU and UK regulatory regimes. It deals with the whole life cycle of psychedelic and medical cannabis businesses from start-up to exit, advising clinics, charities, clinical researchers and international wellness organisations, as well as distributors and other parts of the supply chain. Mackrell.Solicitors' practice focuses on regulatory advice and solutions, licensing and agreements, import, and product compliance, promotion and governance.

Contributing Editors

Elliott Rolfe founded the Psychoactive Medicines Law and Regulatory team at Mackrell.Solicitors and specialises in regulatory solutions and intervention, product and promotional compliance, and licensing and commercial agreements. Having studied psychoactive plant medicines and the therapeutic context in which they operate, he has been able to assist some of the world's leading psychedelics researchers, medical cannabis companies and international charitable organisations, as well as work with all corners of the industry. Elliott has a keen interest in psychedelic therapeutics and drug policy reform and is a long-standing supporter of national initiatives promoting these related fields.

Harry Lancaster is a solicitor in the Psychoactive Medicines Law and Regulatory team at Mackrell.Solicitors, with a special focus on providing corporate and commercial advice to Mackrell.Solicitors' psychedelics and medical cannabis clients. Harry's involvement in the sector goes beyond the specifically legal to include policy initiatives and engagement with the wider industry. Outside his work as a solicitor, Harry volunteers with a number of harm reduction and evidence-based drug reform organisations, including the Psilocybin Access Rights campaign and PsyCare UK.

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Global Overview of Psychedelic Medicines in 2024

Once dismissed as relics of counterculture, psychedelic medicines are now poised to rewrite the future of mental health care – straddling a line between scientific breakthrough and legal frontier. This guide aims to provide both the layperson and the legal practitioner with a comprehensive picture of the current state of the "market" for psychedelic medicines. Quotation marks are used in this instance because the market is still very much in its infancy.

Spravato (produced by Johnson & Johnson) is currently the only licensed psychedelic medicine and some would contend that ketamine, from which it is derived, is not strictly a psychedelic. However, USD780 million-worth of sales in the first nine months of 2024 – a 62% increase from the same period in 2023, continuing a similar trend from 2022–23 – is a sign that there is indeed a market. The market for other psychedelics, such as it is, is a market in which to set up and invest in the drug development companies that hope to create their own Spravato-style success story with treatments that are currently in clinical trial phases.

This nascent phase for the sector brings uncertainty but also significant opportunities. Its success will largely rest on the ability to turn incredibly promising clinical trial results into viable, profitable medicines. Historically, psychedelic medicines have had the complicating factor of their drug element being combined with psychotherapy. Regulators have struggled to understand how best to categorise this element of the treatments, with the US Food and Drug Administration (FDA) stating that "[we] do not regulate therapy". It has also added significantly to the potential cost, as has the long-acting nature of the treatment – an MDMA therapy session can take eight hours and requires two licensed clinicians. Efforts are being made in the sector to create shorter-acting treatments without, or with minimal, psychotherapy elements. It remains to be seen how these will pan out.

The sector has historically also had to contend with considerable hype and the attendant ups and downs as expectations and reality fluctuate around one another. However, with an increasing number of potential drugs in the final phases of development and some of the issues with utopian early approaches being resolved, pragmatic realism has begun to establish itself. That being said, much of this pragmatic realism is required

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from an investor or practitioner's perspective, given that it is likely to be 2026 at the earliest before any of the current crop of companies participating in Phase III trials are able to get a drug to market.

The guide will cover the following jurisdictions and their legal frameworks in depth:

- the UK;
- Brazil;
- the USA;
- Canada; and
- Japan.

What are psychedelics?

"Psychedelic" is a label traditionally attached both to certain compounds found naturally within plants and fungi and to synthetic compounds largely discovered in the mid- and early-20th century that were found to have similar properties. The natural compounds have been used in indigenous medicine for hundreds – if not thousands – of years and their more recent man-made cousins were also originally used therapeutically before the introduction of the United Nations conventions on controlled substances curtailed their use and research into them.

Since research on psychedelic compounds restarted in the 1990s, the beginning of what has come to be called the "psychedelic renaissance", further evidence has been found for their therapeutic use. There has been a subsequent rush to develop novel psychedelics for medicinal use (and even "pseudodelics", designed to convey the same benefits without the "trip").

Psychedelic compounds tend to share the following characteristics.

- They have historically been controlled substances in law under the United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs (the "Single Convention on Narcotic Drugs") (1961), the United Nations Conference for the Adoption of a Protocol on Psychotropic Substances (the "Convention on Psychotropic Substances") (1971), and the specific laws of individual jurisdictions.
- They have particular psychoactive effects with a certain commonality that led to the label "psychedelic", derived from the Ancient Greek words for "mind-manifesting". These effects are usually (but not always) derived from their agonism of the 5HT2A receptor in the brain and peripheral nervous system and are characterised by alterations in sensory input and the processing of sensory information, often causing strong emotional reactions. Effects are highly variable and depend on dose, individual factors, and setting. The experience of users who have taken a psychedelic substance is often referred to as a "trip".
- Under the right circumstances, they can provoke powerful apparent insights, as well as emotional processing and release. This has led to their use in traditional indigenous spiritual and medicinal practices and modern psychological therapies. However, their powerful and often disruptive effect on the mind also carries risks, with users sometimes losing contact with reality and experiencing strong emotions in ways that can be distressing and dangerous. As such, using psychedelics is contraindicated for people with mental health conditions that predispose them to psychosis or other states where they might struggle to connect with consensus reality.

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The most studied psychedelic compounds for medicinal use include:

- psilocybin – the most active compound in so-called magic mushrooms;
- dimethyltryptamine (DMT) – a key active compound in the Amazonian ayahuasca brew);
- 3,4-Methylenedioxymethamphetamine (MDMA) – historically referred to as "Ecstasy");
- lysergic acid diethylamide (LSD); and
- ketamine – a licensed anaesthetic and arguably a psychedelic (although there is no consensus here, as it is not a 5HT2A agonist).

Mescaline, 5-MeO-DMT and ibogaine (also not primarily classified as a 5HT2A agonist) have also been the subject of studies.

Use of psychedelics as medicines

Research into psychedelic compounds as medicines began in the 1950s with investigations into the therapeutic potential of LSD, which was first synthesised by Albert Hoffman in 1938. Research was later done into the therapeutic use of MDMA in the 1970s (MDMA had been first discovered in 1912 for a different medical purpose).

The advent of the "War on Drugs" meant that research and wider investigation largely came to a standstill until the 1990s, when Rick Strassman's US government-funded research into DMT paved the way for the re-emergence of psychedelic research. Since then, there has been a "psychedelic renaissance", and at present there are in the region of 100 Phase I–III trials taking place globally on psilocybin alone.

A distinctive quality of psychedelic compounds as medicines is the broad range of indications where they show significant promise. By way of example, psilocybin has been investigated in relation to major depressive disorder (MDD), post-traumatic stress disorder (PTSD), anxiety disorders, obsessive-compulsive disorder (OCD), substance use disorders, cluster headaches and migraines, eating disorders, cancer-related psychiatric distress, Bipolar Disorder, Alzheimer's disease, Parkinson's disease, chronic pain conditions, and Lyme disease post-treatment symptoms.

As discussed earlier, there is currently only one licensed psychedelic medicine, Johnson & Johnson's Spravato – although some would argue it should not be classed as a psychedelic, given that this is a ketamine-derived medicine. There are four further potential medicines that are at the Phase III clinical trial stage:

- Lykos Therapeutics' midomafetamine (MDMA) medicine for PTSD (currently in the regulatory review stage, with a theoretical extra Phase III to be completed following rejection of their new drug application (NDA) by the FDA;
- Compass Pathways' COMP360 (psilocybin) medicine for treatment-resistant depression;
- Usona Institute's psilocybin medicine for MDD; and
- Awakn Life Sciences' ketamine medicine for alcohol use disorder.

Legal landscape for psychedelic medicines

As can be seen from the guide's authors, psychedelic compounds are classed by most jurisdictions as controlled substances, often largely as a result of the Convention on Psychotropic Substances (1971). This had the general effect of seriously delaying and curtailing research into the therapeutic benefits of these substances globally and is an issue that individual jurisdictions have grappled with in different ways. The individual jurisdiction chapters of this guide

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provide further details on the specific scope of criminal law as it applies to psychedelics.

One ramification of the restricted nature of these substances is that carrying out medical research into their benefits has been hampered by their scheduling. (Scheduling is separate from their legal "class" and reflects the restrictions placed on a substance in the context of public health policy rather than criminal law.) Restrictive scheduling has also generally limited the ability of physicians to prescribe psychedelics as unlicensed medicines. In some ways, this has not had a significant impact on the widespread use of psychedelic compounds in mainstream medicine, as widespread adoption and use is generally dependent on a medicine being licensed within that jurisdiction. The individual chapters will also explore the regime requirements for becoming a licensed medicine.

Attempts to reform the legal categorisation of psychedelics in order to facilitate research and pave the way for adult-use markets have been ongoing in a number of jurisdictions, as public perception and the historic approach to psychedelics have increasingly diverged. In many countries, polling has even revealed that a majority of the public are receptive to the idea of restrictions on psychedelics being relaxed in order to facilitate their use as medicines. Regulators have generally been slow to respond – although significant steps have been made in a number of jurisdictions during the past few years.

In some countries, cannabis has provided a model both for reformers and regulators when it comes to how best to go about updating the legal treatment of psychedelic compounds to make it fit for the 21st century. However, even though it is tempting for those not well acquainted with their differences to lump them together, there are significant divergences in the cultures and risk/benefit profiles of cannabis and psychedelics that need to be considered. There does seem to be no doubt, though, that liberalising attitudes to cannabis have helped to encourage reconsideration of some of the more lurid cultural assumptions about psychedelic compounds. That being said, adult-use markets are likely still some way off for most jurisdictions.

As with cannabis, the USA has been most proactive in taking the lead with psychedelic deregulation and – as is also the case with cannabis – progress at the state level has outpaced the federal level. As a bellwether for the rest of the world, progress in the USA is likely to be a leading indicator for where things are headed. However, even at the state level, the reception for psychedelics has been more muted than that for cannabis – reflecting the differing level of cultural penetration of these different substances.

Public perceptions of psychedelics are still somewhat coloured by the moral panic of the 1960s and 1970s, when unsubstantiated stories about psychedelics making users jump from windows or putting holes in their brains were common fare. Of course, there are real risks for a person affected by a significant dose of a psychedelic substance that are not analogous to most other controlled substances, and therefore it is to be expected that legal paths forwards will be correspondingly cautious. If the latest research has demonstrated anything, however, it is that psychedelic treatments are overwhelmingly more likely to save a recipient from the proverbial window ledge or help a brain heal from the impact of trauma.

BRAZIL

Law and Practice

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Dannemann Siemsen comprises a team of experts dedicated to defending IP since 1900. Recognised as leaders in Latin America, the firm operates throughout the world and offers first-rate IP services and litigation, covering all industry segments as well as attending to IP firms from all different regions. Dannemann Siemsen's patent team – the largest in Brazil – combines experts with a different technical background that allows it to develop the most comprehensive strategies to protect clients' innovations. The firm's trade mark department uses advanced technology to handle clients' cases from searches to appeals, with strategic thinking for trade mark portfolio management and supervision structures, including with regard to digital media. It has more than 120 years of experience built in human knowledge, respect, ethical values, diversity, and a continuous pursuit of staying one step ahead of future changes.

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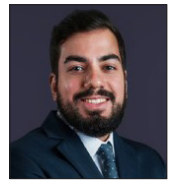

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1. Regulatory Overview

1.1 Primary Laws and Regulations

The main laws and regulations relating to psychedelic medicines in Brazil are:

- Law No 6,360/1976 – provides regulation for health surveillance of medicines, drugs, pharmaceutical ingredients, cosmetics, sanitisers and other products;
- Law No 9,279/1999 – established the National System of Health Surveillance (*Sistema Nacional de Vigilância Sanitária*, or SNVS) and created the Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária*, or ANVISA);
- Law No 9,961/2000 – created the National Regulatory Agency for Private Health Insurance and Plans (*Agência Nacional de Saúde Suplementar*, or ANS);
- Law No 10,742/2003 – provides regulatory standards for the pharmaceutical sector and created the Drugs Market Regulation Chamber (*Câmara de Regulação do Mercado de Medicamentos*, or CMED);
- Law No 11,343/2006 (the "Anti-Drugs Law") – established the National System of Public Policies on Drugs (*Sistema Nacional de Políticas Públicas sobre Drogas*, orSisnad), provides measures for the prevention of misuse, care and social reintegration of drug users and addicts, establishes rules for the repression of unauthorised production and illicit trafficking of drugs, defines crimes, and makes other provisions;
- Ministry of Health (MoH) Ordinance No 344/1998 – technical regulation concerning substances and drugs subject to special control; and
- ANVISA Ordinance No 898/2015 – established a Working Group between ANVISA and the Ministry of Justice to optimise the classification and control of narcotic, psychotropic, precursor and proscribed substances (as well as other substances and plants subject to special control).

ANVISA Resolution of the Collegiate Board (*Resolução da Diretoria Colegiada*, or RDC) No 38/2013 regulates expanded access, compassionate use and post-study drug supply programmes. In summary, ANVISA RDC No 38/2013 establishes the following definitions.

- Expanded access programme – a programme to make available a promising new drug (not yet registered with ANVISA or commercially available in Brazil) that is undergoing or has completed a phase III trial and is aimed at a group of patients who have serious debilitating and/or life-threatening diseases and no satisfactory therapeutic alternative with registered products.
- Compassionate use programme – a programme to allow the supply for personal use by a patient, who is not a participant in an expanded access or clinical research programme, of a promising new drug (not yet registered with ANVISA) that is in the process of clinical development and intended for patients who have serious debilitating and/or life-threatening diseases and no satisfactory therapeutic alternative with products registered in Brazil. The allowance granted by ANVISA for compassionate use is personal and not transferrable.
- Post-study drug supply programme – a programme to allow the continued supply of medicines to research subjects at no cost, applicable in cases of termination of the study or when their participation ends.

ANVISA's approval process for expanded access, compassionate use and post-study

drug supply programmes begins with a request from the sponsor of a clinical trial or the sponsor's representative organisation. Requests for approval of expanded access and compassionate use programmes are analysed by ANVISA according to the following criteria:

- severity and stage of the disease;
- absence of a satisfactory therapeutic alternative in Brazil for the clinical condition and its stages;
- severity of the clinical condition and presence of co-morbidities; and
- assessment of the risk-benefit ratio of using the requested medication.

With ANVISA's permission, the supply of the medicine authorised in the expanded access and compassionate use programmes should be guaranteed as long as there is benefit to the patient, at the doctor's discretion.

1.2 Regulatory Bodies

In Brazil, medicines are governed by a comprehensive and complex regime of legislation and regulations spanning many different areas of law. The legislative and regulatory landscapes are also very dynamic, as government authorities constantly update regulatory processes and policies.

In the Brazilian health regulatory system introduced by Law No 6,360/76, a drug may be marketed only if:

- it has been previously registered with ANVISA, according to Law No 9,782/99; and
- its price has been established by the CMED, as per Law No 10,742/03.

As regards access to drugs, given that the healthcare system is primarily public in Brazil, patients do not have out-of-pocket expenses in most cases, inasmuch as drugs considered to be essential to public health are provided by the Brazilian government. In the private healthcare system, health insurance companies must at least supply patients with drugs included in the List of Procedures issued by ANS.

Accordingly, the main regulatory bodies charged with enforcing the laws and regulations governing the medical psychedelics industry are:

- ANVISA – the Brazilian regulatory body (created in 1999 within the MoH) entitled to enforce public health protections, oversee drug approvals and sanitary standards, regulate the import of drugs, and issue regulatory approval for clinical trials;
- ANS – the regulatory body (created in 2000 within the MoH) responsible for the regulation, standardisation, control and inspection of activities that guarantee private healthcare;
- National Committee for Technology Incorporation (*Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde*, or CONITEC) – the body responsible for advising the MoH in the incorporation or disinvestment of health technologies into the Unified Healthcare System (*Sistema Único de Saúde*, or SUS); and
- National Research Ethics Commission (*Comissão Nacional de Ética em Pesquisa*, or CONEP) – provides ethical review and approval for clinical trials.

1.3 Self-Regulatory Authorities

There are no self-regulatory authorities that govern the psychedelic medicine industry or psychedelic trials in Brazil.

1.4 Existing Market

The Brazilian market of psychedelic drugs is incipient, even though it seems to be gradually evolving by acknowledging the therapeutic potential of psychedelic substances following the development of clinical data and new regulatory approaches on the matter in other jurisdictions.

In a notable regulatory development, ANVISA approved esketamine (S-isomer of ketamine) hydrochloride in 2020 for treating treatment-resistant depression. Ketamine, although not a classic psychedelic, shares some pharmacological properties with this class of substances. The substance had already been used in the past as an anaesthetic in diagnostic and surgical interventions; however, until 2020, it did not have regulatory approval for psychiatric treatment. For further details, please see "Esketamine and ketamine as regulatory precedents" in the Brazilian Trends and Developments chapter of this guide.

In addition, during the past few decades, Brazil has made limited exceptions for traditional and cultural uses of psychedelics. Ayahuasca, a traditional Amazonian brew containing dimethyltryptamine (DMT), has been legally permitted for use within certain religious practices since the 1980s. For more on the case of ayahuasca, please see "Ayahuasca: balancing freedom of religion and drug prohibition" in the Brazilian Trends and Developments chapter of this guide.

However, other psychedelics remain firmly restricted, with minimal legal permissions for research purposes.

1.5 Challenges Facing Market Participants

Brazil is at a critical point in its approach to psychedelic substances as potential treatments for mental health disorders. The historical and regulatory landscape has shaped public perception and legal frameworks, often hindering research and clinical applications. Even though the therapeutic potential of substances such as psilocybin, 3,4-Methylenedioxymethamphetamine (MDMA), and DMT is increasingly recognised, regulatory bodies require compliance with strict rules to ensure patient safety and evidence quality assurance.

Difficulties faced by applicants in obtaining approval to conduct clinical trials with psychedelic substances reinforces the need for regulatory reforms that facilitate research while maintaining safety standards.

2. Cross-Jurisdictional Matters

2.1 Common Cross-Jurisdictional Issues

There are no common or specific cross-jurisdictional issues concerning psychedelic substances in Brazil.

2.2 How Access Is Affected by Foreign Law and Regulation

Even though foreign law and regulation are not applicable in Brazil, the Brazilian regulatory approach to psychedelics has historically mirrored global trends, with strict prohibitions influenced by international drug control conventions. Substances such as lysergic acid diethylamide (LSD), MDMA, psilocybin and DMT were widely classified as illegal amid global drug control efforts, without differentiation between their recreational and potential therapeutic uses. This policy approach placed psychedelics in the

same category as addictive narcotics, imposing restrictions that have hindered research and clinical applications for many years.

3. Legal and Regulatory Developments

3.1 Access to Psychedelic Medicines Today

Brazil's current legislative and regulatory landscapes concerning psychedelic drugs is restrictive. Even though Brazil's regulatory stance on psychedelics reflects a gradual shift shaped by international research developments and the increasing interest in alternative mental health treatments, most psychedelic substances such as LSD, psilocybin, MDMA, mescaline and DMT are categorised as proscribed substances, pursuant to MoH Ordinance No 344/1998 – marking them as prohibited drugs with no authorised therapeutic use.

Applicants for clinical trials are also facing difficulties in obtaining regulatory approval and, ultimately, this jeopardises patients' access to potential treatments. In Brazil, clinical trials are strictly regulated to ensure the safety and efficacy of – and ethical standards for – investigational drugs. For further details, please see "Regulatory barriers to psychedelic research" in the Brazilian Trends and Developments chapter of this guide.

Although access to medical psychedelics does not seem to be a top priority in the regulators' agenda, recent developments (eg, the approval of esketamine for treating treatment-resistent depression mentioned in **1.4 Existing Market**) have set a positive precedent. Such developments suggest that medicines based on psychedelic substances can be approved by ANVISA and made available safely to the population when GCP requirements and the conditions of safety, quality and efficacy are met.

3.2 Legislative Routes to Wider Access

Initial legislative routes should acknowledge the therapeutical potential of psychedelic substances and create mechanisms to allow and foster the conduction of clinical trials and the review of marketing authorisation applications related to psychedelic drugs in an efficient manner while ensuring patient's safety and deterring abusive practices.

Brazil has a robust legislative and regulatory structure in respect of pharmaceutical drugs. However, the challenges involved in the therapeutic use of psychedelic drugs are not addressed in a specific, objective manner.

One example of how the lack of specific, formal regulation focused on the therapeutic use of psychedelic drugs may jeopardise patients' access to potential treatments is the *Instituto Phaneros* case. Owing to the absence of clear provisions on the current regulation, a research organisation called the Phaneros Institute (*Instituto Phaneros*) – focused on the evaluation, research and development of Psychedelic-Assisted Psychotherapy (PAP) in Brazil – struggled to obtain proper authorisations from ANVISA to conduct clinical trials with MDMA and psilocybin for treatment of post-traumatic stress disorder and major depression, respectively.

Instituto Phaneros was only able to compel ANVISA to review the merits of the authorisation applications for the referred clinical trials upon a court order. However, ANVISA eventually denied the applications by concluding that:

- as the research involved the administration of a psychedelic substance to human beings and therefore a high health risk would be involved in the intended activities, the focus of the assessment should be on the prevention of product deviation and on the safety conditions for conducting clinical studies, including the safe administration of the product to patients; and
- *Instituto Phaneros* would have not complied with all regulatory requirements to demonstrate safety in the administration to patients, as well as in the handling, safe-keeping and disposal of the psilocybin substance.

For further details and analysis of the *Instituto Phaneros* case, please see "Instituto Phaneros case: strict requirements for psychedelic research" in the Brazilian Trends and Developments chapter of this guide.

3.3 Adult-Use Markets

Currently, the chances of a regulated "adult-use market" for psychedelic substances in Brazil seem to be low. There has been some deliberation in the sense of decriminalising possession of prohibited substances for personal use – for example, June 2024, the Supreme Court decided to decriminalise marijuana possession for personal use and set the amount at up to 40 grams or six female plants to differentiate the user from the trafficker. Nonetheless, the Brazilian Congress is reviewing Constitutional Bill No 43/23, which aims at including a provision in the Federal Constitution stating that it is a crime to possess or carry any quantity of drugs or narcotics "without authorisation or in disagreement with a legal or regulatory determination".

Given that Brazil's regulatory approach to psychedelics has historically mirrored global trends, it seems the development of regulated markets for the recreational use of psychedelic drugs might encourage increased debate in Brazilian society and, as a consequence, legislative initiatives addressing the matter in the country. However, the absence of legislative initiatives to regulate and foster the therapeutic use of psychedelic substances indicates that it will take a long time for Brazilian authorities – including members of the executive, legislative and judiciary branches – to embark on thoughtful discussions concerning the recreational use of psychedelic substances.

Trends and Developments

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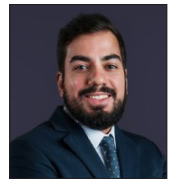

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Regulation of Psychedelic Drugs in Brazil

As mental health challenges continue to rise worldwide, researchers and healthcare providers are exploring alternative treatments beyond traditional drugs. Psychedelics – once dismissed and stigmatised – are undergoing a renaissance within the field of psychiatric treatment. Substances such as psilocybin, lysergic acid diethylamide (LSD) and 3,4-Methylenedioxymethamphetamine (MDMA) are believed to have therapeutic benefits in treating conditions such as depression, anxiety, addiction and post-traumatic stress disorder (PTSD), often where conventional therapies fail.

Brazil, known for its rich biodiversity and unique cultural heritage, has a complex relationship with psychedelics. Indigenous groups have used substances such as ayahuasca ceremonially for centuries, yet regulatory bodies currently impose restrictions on many psychedelic substances, limiting their therapeutic and research potential. With other countries moving towards the regulated use of psychedelics, Brazil faces an opportune moment to reassess its policies and get in touch with the traditional knowledge of its original communities.

The Brazilian Constitution establishes health as a universal right and a state duty, fulfilled through policies that ensure equitable access to healthcare. The Unified Health System (*Sistema Único de Saúde*, or SUS) operates a nationwide network to provide health services, manage public health needs, and incorporate essential medical supplies.

The Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária*, or ANVISA) was created under the Ministry of Health (MoH) to enforce public health protections and oversees drug approvals, sanitary standards, and regulating imports. When a drug is identified as strategic for public health, the National Committee for Technology Incorporation (*Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde*, or CONITEC) – a commission within the MoH – evaluates its incorporation into the SUS after ANVISA's approval. This enables federal, state and municipal healthcare providers to acquire drugs under public bidding regulations, ensuring the drugs' availability to Brazilian citizens.

This article explores the Brazilian situation in terms of psychedelic drug regulation, drawing lessons from international models and considering the future of psychedelic research and therapeutic application in Brazil. For the purposes of this article, the category of psychedelics encompasses both classic (eg, psilocybin, dimethyltryptamine (DMT), mescaline, LSD) and non-classic psychedelic substances (eg, ketamine, MDMA).

Historical context and present challenges

Brazil's regulatory stance on psychedelics reflects a gradual shift, shaped by international research developments and the increasing interest in alternative mental health treatments. This section examines the historical and regulatory journey of psychedelics in Brazil, focusing on existing classifications, current ANVISA policies, and the barriers that researchers face when conducting clinical studies.

Brazil's regulatory approach to psychedelics has historically mirrored global trends, with strict prohibitions influenced by international drug control conventions. Substances such as LSD, MDMA, psilocybin and DMT were widely classified as illegal amid global drug control efforts, without differentiation between their recreational and potential therapeutic uses. This policy approach

placed psychedelics in the same category as addictive narcotics, imposing restrictions that have hindered research and clinical applications.

Ayahuasca: balancing freedom of religion and drug prohibition

During the past few decades, Brazil has made limited exceptions for traditional and cultural uses of psychedelics. Ayahuasca, a traditional Amazonian brew containing DMT, has been legally permitted for use within certain religious practices since the 1980s.

The regulation of ayahuasca for religious purposes in Brazil represents a complex interplay between cultural rights and health governance. In 1985, Brazil's Federal Narcotics Council (*Conselho Federal de Entorpecentes*, or CONFEN) began investigating the religious use of ayahuasca, leading to the eventual permission of its sacramental use by organised religious groups in 1992. This allowance was further protected under the 1988 Brazilian Constitution, which ensures freedom of religion.

CONFEN conducted studies that recognised the cultural and social significance of ayahuasca in religious practices, particularly in the *União do Vegetal* and *Santo Daime* religions. This has contributed to its ongoing legal acceptance.

However, the regulation of ayahuasca maintains strict parameters – including prohibiting commercialisation and exportation – to prevent potential abuse and diversion from spiritual contexts. Also, any diversion from the sacramental and religious use of ayahuasca could potentially lead to the agents involved being charged with crimes under the Anti-Drugs Law (Law No 11,343 of 23 August 2006).

The case of ayahuasca represents a nuanced approach within Brazilian regulation, acknowledging the significance of psychedelics in traditional ceremonies. Nonetheless, other psychedelics remain firmly restricted, with minimal legal allowances for research purposes.

Current classification: MoH Ordinance No 344/1998

ANVISA oversees the regulation of controlled substances in Brazil, including psychedelics. ANVISA's primary framework for these substances is outlined in MoH Ordinance No 344/1998, which classifies controlled substances based on their therapeutic potential and risk profile.

The classification defines substances as narcotic (Lists A1 and A2), psychotropic (Lists A3, B1, B2), other substances subject to special control (List C1), retinoic (List C2), immunosuppressive (List C3), anabolic (List C5), substances that are precursors to narcotics and/or psychotropic substances (List D1), chemical inputs used for the manufacture and synthesis of narcotics and/or psychotropic substances (List D2 – Subject to Control by the Ministry of Justice and Public Security), proscribed plants and fungi that can produce narcotic and/or psychotropic substances (List E), and prohibited substances in Brazil (List F).

The list of prohibited substances in Brazil encompasses narcotic substances (List F1), psychotropic substances (List F2), precursor substances (List F3), and other substances (List F4). Currently, psychedelics such as LSD, psilocybin, MDMA, mescaline and DMT are categorised as F2 substances, marking them as prohibited drugs with no authorised therapeutic use.

i) Challenges in updating MoH Ordinance No 344/1998: New Psychoactive Substances (NPS)

New Psychoactive Substances (NPS), as defined by the United Nations Office on Drugs and Crime (UNODC), are synthetic compounds designed to mimic the effects of controlled drugs such as cannabis, LSD, and methamphetamine. These substances evade current drug regulations, emerging rapidly in global markets and complicating enforcement efforts. Between 2009 and 2021, more than 1,124 NPS were identified, highlighting the challenge of keeping MoH Ordinance 344/1998 up to date.

To address these challenges, Brazil's Ordinance No 898/2015 established a Working Group – comprising experts from ANVISA, the Ministry of Justice and federal law enforcement agencies – to enhance the regulatory model for classifying controlled substances. This group aims to expedite the detection and classification of NPS, utilise collaboration with forensic labs through notification forms, and streamline NPS' inclusion in controlled substances lists.

Regulatory barriers to psychedelic research

In Brazil, clinical trials are strictly regulated to ensure the safety and efficacy of – and ethical standards for – investigational drugs. ANVISA requires all clinical trial protocols for drugs to follow rigorous guidelines aligned with international Good Clinical Practice (GCP) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). ANVISA Resolution of the Collegiate Board (*Resolução da Diretoria Colegiada*, or RDC) No 09/2015 harmonises local regulation with global standards, streamlining the approval process and setting fixed review times for Clinical Development Dossiers.

The National Research Ethics Commission (*Comissão Nacional de Ética em Pesquisa*, or CONEP) collaborates closely with ANVISA by providing ethical review and approval of clinical trials. Whereas ANVISA evaluates the scientific and methodological integrity of studies, CONEP ensures ethical compliance by safeguarding participant rights and overseeing informed consent protocols. All clinical trials must receive joint approval from both ANVISA and CONEP before commencement, demonstrating a dual regulatory framework that enhances study oversight and participant protection.

For researchers to conduct clinical trials involving controlled substances (including psychedelics), they must obtain special permissions from ANVISA and other regulatory bodies. Each will require detailed safety protocols and justification for the study's potential benefits.

By way of example, in order to carry out activities involving substances subject to special control (listed in MoH Ordinance No 344/1998), a private company must obtain a Special Authorisation (*Autorização Especial*, or AE) from ANVISA by proving specific technical and administrative requirements, as set out in ANVISA RDC No 16/2014. In the case of proscribed substances – which includes psychedelic substances – and the plants from which they originate, as well as the proscribed plants (according to Annex I of MoH Ordinance No 344/1998), study and research activities will only be allowed when duly authorised by ANVISA by means of a Special Simplified Authorization for Teaching and Research Establishments (*Autorização para Ensino e Pesquisa*, or AEP) (ANVISA RDC 16/2024, Article 4, paragraph 3).

i) Instituto Phaneros case: strict requirements for psychedelic research

In 2022, ANVISA restricted the requirements for obtaining an AEP by limiting the definition of "teaching and research establishments" to cover only "higher education or technical institutions (including their support foundations) that operate in the strictly academic sphere" (ANVISA RDC 659/2022, Article 4, Item VI), which would basically allow only universities and higher education institutes to engage in research involving proscribed substances. Consequently, research organisations that did not operate in the strictly academic sphere lost the prerogative to conduct study and research activities with proscribed substances.

One of those research organisations was the Phaneros Institute (*Instituto Phaneros*), an institute focused on the evaluation, research and development of Psychedelic-Assisted Psychotherapy (PAP) in Brazil. Prior to the new restriction imposed by ANVISA on which institutions could be allowed to engage in research activities with proscribed substances, ANVISA granted two AEPs to *Instituto Phaneros*:

- AEP No 012/2016 concerning authorisation for research entitled "Psychotherapy assisted with 3,4 Methylenedioxymethamphetamine (MDMA) in the treatment of post-traumatic stress disorder"; and
- AEP No 004/2019 concerning authorisation for research entitled "Psilocybin in the treatment of major depression: Phase 2 pilot clinical trial".

In view of the new restriction imposed by ANVISA RDC No 659/2022, ANVISA began to deny AEP applications submitted by *Instituto Phaneros*, which – as a result – would make all the research projects unfeasible. In parallel, ANVISA suggested that the institute should request an AE, which would be the course of action if the activities were being conducted by a private company.

In response, *Instituto Phaneros* filed a lawsuit against ANVISA seeking to invalidate the new restriction that required the institute to be a "higher education or technical institution" to obtain the AEP in order to move forwards with its PAP trial related to psilocybin. The trial judge granted the request to order ANVISA to review the merits of the AEP application, prohibiting the summary rejection that was based solely on the grounds that *Instituto Phaneros* was not a "higher education or technical institution" and therefore could not request the referred authorisation.

In response, ANVISA submitted a Technical Opinion with its considerations on the merits of the administrative request – in which the regulatory entity maintained its decision to deny the AEP application. ANVISA performed a strict analysis of the documentation submitted by *Instituto Phaneros* and concluded that – seeing as the research involved the administration of a psychedelic substance to human beings and therefore a high health risk would be involved in the intended activities – the focus of the assessment should be on the prevention of product deviation and on the safety conditions for conducting clinical studies, including the safe administration of the product to patients.

After reviewing the technical conditions of the study, ANVISA denied the AEP application, owing to:

- the lack of crucial information to ensure the control of substances subject to special control, as there was no information on the locations where the studies would be conducted;

- the lack of knowledge of the manufacturer of the substance – which would only be defined at the time of the importation – preventing the qualification of the supplier/exporter of the product and jeopardising the feasibility of complying with the international trade in controlled substances;
- the lack of presentation of the contracts between the companies that would perform the customs procedures for the release of the imported products at the customs terminals and perform the transportation of the investigational product;
- the lack of a standard procedure for qualifying companies (including the lack of contract with transportation and cleaning services companies);
- the lack of validation of the electronic spreadsheet for controlling product distribution, demonstrating a failure to comply with all the necessary steps to guarantee product traceability;
- non-conformity in identification of the cupboard used to store the products;
- stock of substances – corresponding to two years of consumption – exceeding the quantities foreseen to meet the needs of six months of consumption, in non-compliance with MoH Ordinance No 344/1998;
- the lack of preventive action that periodically assesses the robustness of security systems; and
- the lack of a standard procedure for hiring employees, such as a judicial background check.

In addition, ANVISA highlighted that the projects presented in the AEP request involved other institutions that (like *Instituto Phaneros*) would have to comply with all regulatory requirements to demonstrate safety in the administration to patients, as well as in the handling, safe-keeping and disposal of the psilocybin substance. Therefore, all 14 clinics where the substance was intended to be administered should have had authorisation from ANVISA to engage in activities involving controlled substances – which they did not have.

ANVISA's response in the *Instituto Phaneros* case demonstrates the caution with which studies involving psychedelics have been treated by the agency, especially in view of the high risk associated with both patient safety and the fear of products being misused.

The *Instituto Phaneros* case also presents another level of complexity that ANVISA must learn to navigate – namely, the association of a drug treatment with psychotherapy. In the Food and Drug Administration (FDA)'s Guidance for Industry entitled "Psychedelic Drugs: Considerations for Clinical Investigations", the American regulatory agency states: "Many of the psychedelic drug development program[me]s involve administering the investigational drug and then engaging in psychological support or psychotherapy either while the subject is experiencing the acute effects of the drug or in a subsequent session. This additional variable both complicates the assessment of effectiveness and presents a challenge for any future product labeling."

According to the FDA, this is because "psychotherapeutic interventions have the potential to increase expectancy and performance biases" and, as such, "sponsors should plan to justify the inclusion of a psychotherapy component and describe any trial design elements intended to reduce potential bias or to quantify the contribution of psychotherapy to the overall treatment effect".

Owing to the restricted status, the extensive documentation required for obtaining the necessary licences, the complexities of specific study designs, and the understandable difficulties in acquiring the necessary substances for research, these procedural challenges could potentially limit the number of clinical trials conducted domestically.

Considering the potential that psychedelics may have for the treatment of mental disorders and considering the increased interest of both the public and the industry in drugs based on psychedelic substances, it is expected that – in the coming years – ANVISA (like the FDA) will begin to issue communications, guides, decisions, and new regulations on the performance of research with psychedelics in Brazil.

Esketamine and ketamine as regulatory precedents

In a notable regulatory development, ANVISA approved esketamine (S-isomer of ketamine) hydrochloride in 2020 for treating treatment-resistant depression. Ketamine, although not a classic psychedelic, shares some pharmacological properties with this class of substances. The substance had already been used in the past as an anaesthetic in diagnostic and surgical interventions; however, until 2020, it did not have regulatory approval for psychiatric treatment.

Formerly classified as part of List C1 (other substances subject to special control), ketamine received its reclassification to List B1 (psychotropic substances with medical use) in 2022 – as did esketamine. Along with the modification of the regulatory status of the substances, ANVISA also included in MoH Ordinance 344/1998 two requirements for ketamine and esketamine-based drugs:

- that pharmaceutical drugs containing the substances ketamine and esketamine may only be dispensed and taken in healthcare establishments; and
- that pharmaceutical drugs containing the substance esketamine as a nasal spray must be administered in healthcare facilities under the observation of a healthcare professional and the patients must be monitored until they are considered clinically stable and ready to leave the facility.

The requirement of controlled settings and strict guidelines for prescription and administration, which is also in place in other countries, helps to prevent abuses and mitigate the risk of serious adverse outcomes resulting from sedation and dissociation.

The approval of esketamine in Brazil marked a significant step in the regulatory landscape for alternative treatments of mental health conditions.

Perspectives on IP rights and biodiversity

Brazil's Intellectual Property Law (Law No 9,279/96) allows novel compounds, formulations and processes to be patented if they meet the requirements of novelty, inventive step, and industrial applicability. The increasing interest in psychedelic substances for therapeutic applications – such as psilocybin for treating depression, MDMA for alleviating PTSD, and DMT for addressing various mental health issues – has fuelled research and development efforts in this field.

However, defining what qualifies as a "new" invention becomes intricate when it involves naturally occurring substances. Even though synthetic variations of psychedelics may be eligible for patent protection, naturally sourced

compounds are often included in the exceptions that prevent the patenting of biological materials found in nature. This situation poses significant challenges for Brazil's patent system as it seeks to balance the need to protect innovation while ensuring access to traditional knowledge, especially in relation to indigenous and traditional communities that have been using these substances for centuries.

In this context, Brazil's Biodiversity Law (Law No 13,123/2015) could play a relevant role. This legislation regulates access to genetic resources and the associated traditional knowledge, mandating that any use of biodiversity must be conducted with prior informed consent from indigenous communities and must ensure fair and equitable sharing of benefits derived from such resources. The Biodiversity Law adds another layer of complexity to the patenting process by requiring that patent applicants disclose the origin of the genetic material used in their inventions and comply with the rules surrounding access and benefit-sharing.

Conclusion

Brazil is at a critical point in its approach to psychedelic substances as potential treatments for mental health disorders. The historical and regulatory landscape has shaped public perception and legal frameworks, often hindering research and clinical applications. Although the therapeutic potential of substances such as psilocybin, MDMA and DMT is increasingly recognised, regulatory bodies require compliance with strict rules to ensure patient safety and evidence quality assurance.

The *Instituto Phaneros* case highlights the need for regulatory reforms that facilitate research while maintaining safety standards. The approval of esketamine sets a positive precedent, suggesting that – when GCP requirements and the conditions of safety, quality and efficacy are met – medicines based on psychedelic substances can be approved by ANVISA and made available safely to the population.

By reassessing current classifications and restrictions, Brazil can foster a regulatory environment that promotes innovation and expands access to effective mental health treatments. Ultimately, this will benefit its citizens and enhance overall public health.

CANADA

Law and Practice

Contributed by:
Robert W.E. Laurie
AD LUCEM LAW CORPORATION

Contents

AD LUCEM LAW CORPORATION was founded in 2013 by Robert W.E. Laurie, an award-winning international lawyer qualified in England and called to the British Columbia Bar. Robert's legal practice focuses on commercial business, government, regulatory issues, and charter and constitutional legalities surrounding cannabis and psychedelic plant medicines. Robert has many years of policy development, legal practice in corporate, commercial, and administrative law, and licensing, regulatory, and constitutional charter experience concerning medical access to cannabis and psilocybin. As a lawyer in Canada, Robert works to reform drug laws. As a consultant, he devises regulatory, government policy, and business solutions for global companies in the regulated food, cannabis, and psychedelic industries. Robert is a board adviser to the Psychedelic Association of Canada and Heroic Hearts Project and was an adviser with MAPS (Canada) and the Last Prisoner Project.

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Robert W.E. Laurie is a barrister and solicitor. He founded AD LUCEM LAW CORPORATION in 2013, advocating for improved patient access to cannabis, psychedelics, and sacred plant medicines. Robert's legal practice focuses on commercial business, government, regulatory issues, and charter and constitutional legalities. He advised Dr Bruce Tobin and TheraPsil Alliance's Section 56 CDSA psilocybin exemption case. Robert co-drafted the Decriminalize Nature Canada Petition, part of a national campaign to decriminalise restricted plant medicines. An acclaimed international speaker, he presents on cannabis, psychedelics, and entheogens at global conferences. He holds an MA Juris from the University of Oxford (St Edmund Hall) and a BA (Hons) in Political Science and International Relations from the University of British Columbia (UBC).

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1. Regulatory Overview

1.1 Primary Laws and Regulations

In Canada, psychedelic substances are regulated under three primary laws: the Cannabis Act, the Controlled Drugs and Substances Act (CDSA), and the Food and Drugs Act (FDA). While cannabis is fully legal for adult use, other psychedelics like psilocybin, LSD, DMT, and MDMA remain illegal under the CDSA, except in specific cases where exemptions are granted under Section 56 of the CDSA or through Health Canada's Special Access Program (SAP). These programmes allow for limited, compassionate access to psychedelics for medical or scientific purposes, particularly for patients with serious or life-threatening conditions. However, the process is highly restrictive, with most applicants facing significant hurdles, including time-consuming applications and frequent rejections, limiting broader access to these substances. Additionally, British Columbia has decriminalised small-scale possession of MDMA and other substances as part of a harm reduction initiative.

1.2 Regulatory Bodies

In Canada, several regulatory bodies are responsible for enforcing the laws governing medical psychedelics:

- Health Canada: This federal agency oversees the enforcement of the CDSA and the Food and FDA. Health Canada manages the SAP, which provides compassionate access to restricted substances like psilocybin and MDMA for medical use in serious or life-threatening conditions. Health Canada also grants Section 56 exemptions for medical or scientific purposes, allowing controlled use of otherwise illegal substances.
- Provincial health authorities: These bodies ensure that medical professionals comply with provincial health regulations, particularly regarding patient care and prescription practices. They work in conjunction with Health Canada to ensure that psychedelic therapies, when permitted, meet medical and ethical standards.
- Law enforcement agencies: Local and federal law enforcement, such as the Royal Canadian Mounted Police (RCMP) and municipal/provincial police, are responsible for ensuring compliance with federal and provincial drug laws. Their scope includes investigating illegal activities such as unauthorised sale or distribution of psychedelics and enforcing regulations around medical exemptions and legal dispensaries.
- Canada Border Services Agency (CBSA): CBSA regulates the import and export of controlled substances under the CDSA. They ensure that psychedelic substances crossing Canadian borders comply with legal exemptions and permits, including those for scientific or medical research.

Each of these bodies plays a role in ensuring that the medical use of psychedelics is carefully regulated, balancing access to therapies with public safety and legal compliance.

1.3 Self-Regulatory Authorities

Currently, Canada does not have a formal self-regulatory authority specifically governing the psychedelic medicine industry or psychedelic trials. However, several organisations play influential roles in shaping standards and practices for the emerging psychedelic field:

- Multidisciplinary Association for Psychedelic Studies Canada (MAPS Canada): Although not a regulatory body, MAPS is a prominent non-profit organisation involved in funding and conducting psychedelic research,

particularly for MDMA-assisted therapy. MAPS Canada works closely with regulators like Health Canada to ensure compliance with research standards and advocates for the integration of psychedelics into medical practices.
- Psychedelic Association of Canada (PAC): The PAC acts as a hub for professionals, researchers, and advocates in the psychedelic space. It promotes ethical practices, harm reduction, and public education. While the PAC has no direct regulatory authority, it influences the self-regulation of the industry by promoting responsible use and working to develop industry standards.
- TheraPsil: Another non-profit organisation, TheraPsil focuses on advocating for access to psilocybin-assisted therapy, primarily for patients in palliative care. While not a regulator, TheraPsil helps guide healthcare professionals and patients in navigating the complex legal landscape surrounding psychedelic therapy through training and advocacy.
- Roots to Thrive: Canada's first multidisciplinary, non-profit healthcare practice offering evidence-informed, multi-week group therapy programmes, including ketamine-assisted therapy. Guided by principles of trauma-informed practice, anti-racism, health promotion, and holistic care, Roots to Thrive tackles the root causes of illness and reduces stigma while fostering interconnectedness and spiritual health.

These organisations help foster best practices and ethical frameworks within the psychedelic medicine industry, advocating for safe and effective use of psychedelics, but they operate within the larger framework of Canadian law, without formal regulatory power.

1.4 Existing Market

In Canada, the market for psychedelic substances is still emerging and operates largely in a grey area, with legal access limited to clinical trials, compassionate use through Health Canada's SAP, and exemptions under Section 56 of the CDSA. There is no fully legalised market for psychedelics like there is for cannabis, but certain activities indicate a growing interest in both medical and underground markets.

- Medical market: Legally, the medical market is focused on clinical trials and highly regulated programs like the SAP. Patients with serious or life-threatening conditions can apply through their healthcare provider for limited access to psychedelics such as psilocybin or MDMA for therapeutic purposes. However, the process is cumbersome, and access is restricted, limiting the size of the formal medical market.
- Underground and illegal market: Despite the legal restrictions, there has been a rapid growth of illegal psychedelic dispensaries, particularly in cities like Vancouver and Toronto. These stores openly sell products like psilocybin in the form of mushrooms, edibles, and other formulations, often packaged in sleek, consumer-friendly ways. While these dispensaries operate illegally, local law enforcement in some areas has taken a relatively hands-off approach, allowing the market to expand despite the legal risks.
- Psychedelic retreats and clinics: Though not a widespread market yet, Canada is seeing a rise in clinics and retreats offering ketamine-assisted therapy, which is legal for medical use. These clinics are often part of the broader mental health treatment sector and reflect growing consumer demand for psychedelic-based therapies. As other psychedelics like psilocybin and MDMA move through clinical

trials, there is potential for this segment of the market to expand significantly.

Overall, while the legal psychedelic market is still in its infancy and restricted to tightly controlled medical uses, an underground market is flourishing in parallel. This dual-market dynamic suggests increasing demand for psychedelic therapies and products, with the potential for significant growth if further legal reforms are enacted.

1.5 Challenges Facing Market Participants

Market participants in the psychedelic industry in Canada face several notable challenges, primarily due to the complex and evolving legal landscape. Here are the key legal risks and challenges companies should consider:

- Regulatory uncertainty: The legal status of most psychedelics, such as psilocybin, LSD, and MDMA, remains highly restricted under the CDSA. Access is typically only granted through Health Canada's SAP or Section 56 exemptions for medical or scientific purposes. Companies attempting to engage in clinical research, production, or distribution must navigate a complex and often slow regulatory approval process. The lack of clear pathways for broader commercialisation makes long-term planning difficult.
- Enforcement risk: While certain cities (like Vancouver) have seen lenient enforcement regarding illegal psychedelic dispensaries, these operations remain fully illegal under federal law. Participants in the underground market risk raids, asset seizures, fines, and criminal charges. Law enforcement's inconsistent approach across jurisdictions further complicates matters, creating unpredictability in how laws will be enforced.
- Compliance with Health Canada: For companies involved in clinical trials or legal psychedelic therapies, strict adherence to Health Canada's regulations is critical. This includes obtaining appropriate licenses, maintaining high standards of safety, and following protocols for drug production, distribution, and patient treatment. Non-compliance can result in the suspension of trials, fines, and other penalties, as well as reputational damage.
- Limited access to capital and banking services: Due to the legal uncertainty surrounding psychedelics, many financial institutions are hesitant to work with companies in this sector. This limits access to banking services, loans, and investment capital. Similar challenges were faced by the cannabis industry in its early stages, where companies struggled to secure funding from traditional financial institutions.
- Intellectual property and patents: Since many psychedelic substances, especially in their natural forms (eg, psilocybin mushrooms), cannot be patented, companies face challenges in securing intellectual property protection. This limits their ability to create competitive advantages through proprietary formulations or therapies. Companies investing heavily in research and development may struggle to recoup their costs without strong IP protections.
- Public and market perception: Psychedelics are still heavily stigmatised in some sectors of society, and companies entering this market face reputational risks. Public opinion can influence regulatory decisions and consumer demand, making it important for companies to engage in educational and advocacy efforts to promote the therapeutic benefits of psychedelics and counter negative stereotypes.

- Ethical and legal responsibility in treatment settings: Clinics offering legal psychedelic therapies (such as ketamine) must navigate ethical challenges, including ensuring proper screening of patients, providing adequate supervision, and mitigating risks of adverse reactions. Failure to uphold high standards of care could lead to legal liabilities, including malpractice claims.

In conclusion, companies in the psychedelic industry must be aware of the legal risks involved, from navigating complex regulatory frameworks to managing reputational and financial challenges. Careful planning, compliance, and legal counsel are essential for operating safely and successfully in this emerging sector.

2. Cross-Jurisdictional Matters

2.1 Common Cross-Jurisdictional Issues

Cross-jurisdictional issues are common in the emerging psychedelic industry due to the varying legal frameworks across different regions. Some of the key challenges include:

- Inconsistent legal status of psychedelics: In Canada, psychedelics like psilocybin and MDMA are illegal under the CDSA, except under specific exemptions for medical or research purposes. Meanwhile, in other countries, particularly in parts of the USA such as Oregon and Colorado, psychedelics are legal or decriminalised for medical or therapeutic use. This creates complications for companies operating across borders, as substances legal in one jurisdiction may be strictly prohibited in another.
- Cross-border research and clinical trials: Companies conducting research on psychedelics often face challenges when collaborating internationally. Different countries have varying requirements for the approval of clinical trials and the transportation of controlled substances. Canadian companies seeking to participate in global research initiatives must navigate these regulatory differences, which can cause delays or restrict collaboration.
- Import and export of psychedelic substances: The transportation of psychedelic substances across borders is strictly regulated, and in many cases, prohibited without specific permits. Even for research purposes, companies face complex import/export regulations, both in Canada and in other countries. Non-compliance can result in significant legal consequences, including fines, seizures, and criminal charges.
- Banking and financial services: Due to the different legal statuses of psychedelics in various jurisdictions, many financial institutions are reluctant to provide services to companies operating in this space. For example, a company in Canada may struggle to access banking or investment services if its operations involve jurisdictions where psychedelics are still heavily restricted, such as in the USA. This can limit cross-border growth and investment opportunities.
- Intellectual property and patent protection: The legal protections for psychedelic-related intellectual property vary widely across jurisdictions. Some countries do not allow the patenting of natural psychedelic compounds, while others offer more robust protections. This creates difficulties for companies trying to safeguard their innovations across borders, especially when operating in multiple countries with different IP laws.
- Varying enforcement approaches: Even within Canada, enforcement of psychedelic laws differs by city and province, and this is amplified internationally. For instance, while some

Canadian cities like Vancouver are lenient toward illegal psilocybin dispensaries, other jurisdictions strictly enforce prohibition. Companies operating in multiple jurisdictions must be prepared for differing levels of enforcement and the associated legal risks.
- Ethical and medical standards: The standards for conducting psychedelic-assisted therapy vary widely across regions. For example, what is considered appropriate medical supervision in one country may differ in another. Companies offering psychedelic treatments across borders must ensure compliance with local medical, ethical, and regulatory standards, which can add complexity to their operations.

These cross-jurisdictional issues require companies to maintain a clear understanding of the legal landscape in each country or region where they operate, ensuring compliance with local regulations while managing the risks associated with operating in a highly fragmented and evolving industry.

2.2 How Access Is Affected by Foreign Law and Regulation

Access to psychedelic medicines in Canada is influenced by the laws and progress of psychedelic regulations in other jurisdictions, particularly in the United States and other countries that are advancing in this space. Here are a few key ways this cross-border influence occurs:

- Clinical research and trials: Much of the research on psychedelics, especially MDMA and psilocybin, is being conducted internationally, notably in the USA through organisations like MAPS. Canada often looks to global clinical trial data and research outcomes to inform its own regulatory decisions. If another country demonstrates significant therapeutic benefits through studies or trials, it may encourage Health Canada to consider expanding access through its SAP or Section 56 exemptions.
- Regulatory precedents: Progress made in jurisdictions like Oregon, where psilocybin is now legal for therapeutic use, and Colorado, which is launching its medical psychedelics programme, can set important precedents for Canada. These developments abroad can build momentum for legal reforms domestically, especially if positive outcomes are observed. For example, as more US states decriminalise or regulate psychedelics, there may be increasing pressure on Canadian lawmakers to follow suit.
- Market and industry development: The success of legal markets in other countries, such as the legal psilocybin program in Oregon, can influence the economic and regulatory landscape in Canada. If other jurisdictions establish robust, regulated psychedelic markets, Canadian companies and advocates may push for similar changes to tap into international demand, fostering a more competitive and open market at home.
- Import of best practices: As other countries advance in legalising and regulating psychedelic therapies, Canada may adopt best practices from those jurisdictions. For instance, frameworks around the safe administration of psychedelics, such as training requirements for therapists or protocols for clinics, can be modelled on international successes and help shape Canadian regulations.
- Cross-border collaboration: Canadian researchers and companies often collaborate with international partners, particularly in countries with more advanced psychedelic regulations. These collaborations may drive innovation and influence Canadian policies by demonstrating the safety and efficacy of

psychedelic therapies through international data. Access to international clinical trials or studies can also provide Canadian patients with early opportunities to benefit from psychedelic therapies under compassionate use frameworks.

In conclusion, while Canadian psychedelic laws remain restrictive, progress in other jurisdictions – particularly in the USA and Europe – can have a significant impact on regulatory discussions, research, and eventual access to psychedelic medicines in Canada.

3. Legal and Regulatory Developments

3.1 Access to Psychedelic Medicines Today

In Canada, access to medical psychedelics is primarily governed by the CDSA, the FDA, and Health Canada's regulatory frameworks. Several key legal elements impact access to medical psychedelics:

- Prohibition under the CDSA: Most psychedelics, including psilocybin, LSD, DMT, and MDMA, are classified as illegal under the CDSA. This prohibits their possession, production, and distribution unless authorised under specific exemptions. Medical access is limited to Health Canada's SAP and Section 56 exemptions, which allow the use of controlled substances for patients with serious or life-threatening conditions and for scientific research.
- SAP: The SAP allows healthcare practitioners to request access to otherwise unavailable drugs, including psychedelics, for compassionate reasons. However, the process is slow, restrictive, and only available in exceptional circumstances. The limited nature of SAP approvals means that access remains tightly controlled and available to a small number of patients.
- Section 56 exemptions: These exemptions allow individuals, groups, or researchers to legally use psychedelics for medical or scientific purposes. While Health Canada has granted some exemptions for clinical trials and individual therapies, they are issued sparingly, and the process can be bureaucratic and time-consuming.
- Clinical trials: Access to psychedelics is also possible through participation in clinical trials. However, these trials are limited in scope and availability, making this pathway inaccessible to the broader population. Approval for new trials requires extensive regulatory compliance, further slowing the expansion of access.

Likelihood of Change

The likelihood of these legal elements changing is moderate, driven by a combination of scientific advancements, public pressure, and developments in other jurisdictions, especially in the USA.

- Growing advocacy and research: Increasing advocacy from organisations like MAPS and TheraPsil, combined with promising results from clinical trials on psychedelics' therapeutic benefits, may push regulators to reconsider the current legal restrictions. With MDMA and psilocybin showing positive outcomes in treating PTSD and depression, the regulatory environment is becoming more favourable for expanded access.
- International influence: The progress of psychedelic regulation in places like Oregon and Colorado has set a precedent that may influence Canadian policymakers. As other

countries and US states demonstrate the safe therapeutic use of psychedelics, there will be more pressure on Canada to align with international developments.
- Public and medical interest: Public opinion is slowly shifting in favour of therapeutic psychedelics, and the medical community's growing interest in these treatments may spur regulatory change. However, given the cautious approach of Canadian regulators, any expansion in access will likely be incremental and tied to strict medical supervision.

Regulatory Agenda

The topic of medical psychedelics is increasingly gaining attention among Canadian regulators. While full legalisation or widespread medical access is not yet on the immediate agenda, the following developments suggest it is moving up the list of priorities:

- Senate report on veterans' psychedelic therapy: In 2023, the Canadian Senate published a report advocating for more research into psychedelic-assisted therapies for veterans suffering from PTSD. This marks the first significant government recognition of the therapeutic potential of psychedelics.
- Increased research approvals: Health Canada is approving more clinical trials for psychedelics and granting some Section 56 exemptions, indicating a shift toward recognising the medical potential of these substances.
- Public pressure: Advocacy groups and public demand for alternative treatments are putting pressure on regulators to reconsider the restrictive frameworks. The increasing awareness and success of psychedelic treatments in the USA are likely to push this issue further into the regulatory spotlight.

In conclusion, while the current legal elements still impose significant barriers to access, there is growing momentum toward change. Regulators are becoming more open to the therapeutic potential of psychedelics, but any broad changes will likely be gradual, focusing first on controlled medical use and expanded research opportunities.

3.2 Legislative Routes to Wider Access

In Canada, any initial legislative route to expanding access to medical psychedelics is likely to follow a cautious, incremental approach, similar to the pathway taken with cannabis legalisation. Here is a potential outline of what that legislative route might look like:

SAP and Section 56 Exemptions

The first step in legislative reform would likely involve broadening the existing frameworks under the SAP and Section 56 exemptions. This could include:

- simplifying the application process for healthcare providers and patients to request psychedelic treatments through the SAP for a wider range of medical conditions, not just life-threatening ones;
- expanding Section 56 exemptions to include more patients and research initiatives, particularly for mental health disorders like PTSD, depression, and anxiety, which would allow for a greater number of individuals to legally use psychedelics in clinical settings; and
- encouraging more clinical trials through government incentives or streamlined approval processes to gather additional data on the therapeutic benefits of psychedelics.

Creation of a Medical Psychedelic Framework

As the data from clinical trials and exemptions accumulate, the next step would likely involve creating a formalised medical framework for psychedelics, similar to the early medical cannabis system:

- Medical psychedelic programme: This could allow registered patients to access certain psychedelics under medical supervision for specified conditions. Access might initially be limited to substances like psilocybin and MDMA, which have shown strong therapeutic potential in studies.
- Licensed clinics and therapists: Legislation would likely establish a system of licensed clinics or healthcare providers qualified to administer psychedelics, similar to how ketamine clinics currently operate. Strict training and certification requirements would ensure safe administration.
- Tightly controlled supply chain: Initially, the production and distribution of psychedelics would be heavily regulated, with licensed producers supplying approved clinics. This would mirror Canada's approach to medical cannabis, ensuring quality control and safety.

Harm Reduction and Decriminalisation Measures

In parallel to the medical framework, Canada might also take steps toward decriminalisation and harm reduction. This would involve:

- Decriminalising small possession: Similar to British Columbia's decriminalisation of small amounts of MDMA and other substances, Canada could expand this to include psilocybin and other psychedelics. This would focus on reducing criminal penalties for personal use while still regulating the sale and distribution.
- Harm reduction initiatives: Public health campaigns and harm reduction strategies would likely be implemented to educate the public on safe usage and reduce the stigma around psychedelics.

Controlled Expansion of Legal Access

Over time, with growing evidence of safety and efficacy, the legal framework could expand access to psychedelics:

- Additional conditions: The list of conditions for which psychedelics can be prescribed would likely grow, expanding beyond PTSD and treatment-resistant depression to include anxiety disorders, end-of-life care, and addiction treatment.
- Commercial availability for medical use: Licensed pharmacies or dispensaries may eventually be permitted to sell psychedelics directly to patients with prescriptions, further expanding access and aligning with the growing demand for alternative mental health treatments.

Possible Integration with Indigenous Rights and Traditional Use

Any legislative route in Canada is likely to include consideration for the rights of Indigenous communities, especially regarding traditional use of psychedelics in ceremonial and healing contexts. Legislative frameworks could integrate UNDRIP principles, allowing for regulated access to psychedelics for Indigenous practices and recognising the historical use of these substances.

Timeline and Challenges

- Gradual reform: Given the cautious nature of Canadian drug policy reform, this process is likely to unfold gradually, with medical access

frameworks developed first, followed by broader decriminalisation and harm reduction initiatives.
- Regulatory and public scrutiny: Any legislative route will involve extensive public consultation and scrutiny from regulators to ensure that safety, medical ethics, and societal impact are considered at every stage.

In conclusion, the initial legislative route in Canada would likely involve expanding access through existing frameworks like SAP and Section 56, followed by the creation of a regulated medical programme and eventual decriminalisation. This phased approach would allow regulators to balance public safety with growing demand for psychedelic therapies.

3.3 Adult-Use Markets

The likelihood of a regulated, recreational ("adult-use") psychedelic market emerging in Canada is currently low in the short term but possible in the long term, particularly if the therapeutic use of psychedelics gains widespread acceptance and successful regulatory frameworks are established. Here is an analysis of what such a market could look like and the factors that could influence its development:

Likelihood of an Adult-Use Market

- Current regulatory landscape: At present, psychedelics like psilocybin, MDMA, and LSD are classified as controlled substances under the CDSA. The legal focus is currently on medical and research-based use, with access limited to Health Canada's SAP, Section 56 exemptions, and clinical trials. These frameworks are highly restrictive and show no immediate signs of shifting toward recreational use.
- Comparison to cannabis legalisation: Canada's approach to cannabis legalisation could serve as a precedent for psychedelics. Cannabis was legalised first for medical use, and after years of public debate, court rulings, and changes in public opinion, the adult-use market was established in 2018. If similar patterns hold, a recreational psychedelic market could eventually emerge, though likely after several years of strict medical use and careful research-based regulation.
- Public opinion and advocacy: Public awareness and acceptance of psychedelics are growing, particularly due to the increasing recognition of their therapeutic potential. However, public opinion on psychedelics for recreational use is less developed than it was for cannabis. Advocacy groups are currently focused on medical access, with little push for outright recreational legalisation. Significant public education and cultural shifts would be required before the idea of recreational psychedelics gains widespread support.
- Government reluctance: Canadian regulators are generally cautious when it comes to drug policy reform. Health Canada is still focused on ensuring safe and controlled access to psychedelics for therapeutic purposes. Given the stigma and safety concerns associated with recreational psychedelics, it is unlikely that a regulated adult-use market will be prioritised in the near future. In the long term, if therapeutic programmes are successful and the substances are proven safe under controlled conditions, the government may reconsider its stance.

What a Regulated Adult-Use Market Might Look Like

If Canada were to establish a regulated recreational psychedelic market, it would likely follow a framework similar to cannabis, with strict con-

trols and gradual roll-outs. Here is what such a market might entail:

- Strict regulation and licensing: The government would likely impose strict licensing requirements for production, distribution, and sale, similar to the cannabis industry. Licensed producers would be responsible for cultivating and manufacturing psychedelics, while retail outlets would need government approval to operate. Regulations around quality control, dosing, and packaging would be implemented to ensure consumer safety.
- Controlled access and age restrictions: A recreational market would likely have strict age restrictions, possibly mirroring the minimum age for cannabis consumption (18 or 19, depending on the province). There would also be limits on the quantity of psychedelics an individual could purchase or possess at any given time, along with education programmes focused on responsible use.
- Licensed psychedelic dispensaries: Similar to cannabis, specialised dispensaries would likely be established to sell psychedelics in a regulated environment. These dispensaries would be responsible for ensuring that customers are informed about the effects and risks of psychedelics and that products are sold in a safe, controlled manner.
- Zoning and public consumption laws: The government would likely impose zoning laws to regulate where psychedelics could be sold, as well as restrictions on where they could be consumed. Public consumption might be prohibited, with a focus on private, controlled settings to minimise public health and safety risks.
- Product forms and limitations: Initially, only certain psychedelic substances like psilocybin might be legalised for recreational use. The market would likely focus on lower-potency products, such as dried mushrooms or low-dose formulations, with tighter controls on more potent substances like LSD or MDMA. Microdosing might also be promoted as a safer, more socially acceptable form of recreational use.
- Taxation and government revenue: Similar to the cannabis market, a regulated psychedelic market would generate government revenue through taxes on sales and licenses. These funds could be allocated to public health initiatives, harm reduction programmes, and further research into the safe use of psychedelics.
- Integration of harm reduction programmes: Any recreational framework would likely include strong harm reduction measures. This might involve mandatory education for consumers, training for dispensary staff, and partnerships with healthcare providers to mitigate risks associated with misuse. Safe consumption spaces, similar to safe injection sites, could also be introduced for those using psychedelics in public settings.

Barriers to an Adult-Use Market

- Public health concerns: Psychedelics can have strong psychoactive effects, and there are concerns about their use outside of medical supervision. Unlike cannabis, psychedelics are less understood by the public, and the risks of adverse reactions (such as “bad trips” or psychological harm) are significant concerns for regulators.
- Lack of precedent: While the therapeutic potential of psychedelics is being researched, there is little global precedent for a fully regulated adult-use psychedelic market. Without examples of successful recreational frameworks elsewhere, Canada may be reluctant to lead the way.

- Stigma and perception: The stigma around psychedelics, often associated with the counterculture of the 1960s, still exists. Overcoming this stigma will take time and education, especially given the more serious psychoactive effects of psychedelics compared to cannabis.

Conclusion

In the short to medium term, the likelihood of a regulated adult-use psychedelic market in Canada remains low. The current focus is on expanding medical access and researching the therapeutic potential of psychedelics. However, if these medical frameworks prove successful and public perception shifts, a recreational market could develop over time. Any such market would likely be tightly regulated, mirroring the gradual approach Canada took with cannabis legalisation, with an emphasis on public safety, responsible use, and harm reduction.

Trends and Developments

Contributed by:
Robert W.E. Laurie
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AD LUCEM LAW CORPORATION was founded in 2013 by Robert W.E. Laurie, an award-winning international lawyer qualified in England and called to the British Columbia Bar. Robert's legal practice focuses on commercial business, government, regulatory issues, and charter and constitutional legalities surrounding cannabis and psychedelic plant medicines. Robert has many years of policy development, legal practice in corporate, commercial, and administrative law, and licensing, regulatory, and constitutional charter experience concerning medical access to cannabis and psilocybin. As a lawyer in Canada, Robert works to reform drug laws. As a consultant, he devises regulatory, government policy, and business solutions for global companies in the regulated food, cannabis, and psychedelic industries. Robert is a board adviser to the Psychedelic Association of Canada and Heroic Hearts Project and was an adviser with MAPS (Canada) and the Last Prisoner Project.

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The landscape of psychedelic medicines has undergone significant shifts in recent years. While public perception has evolved, research continues to build on their therapeutic potential, and legal reforms have taken hold in select regions. With increasing attention on psychedelics' potential to address the opioid and fentanyl epidemic by offering alternative treatments for addiction and pain management, the intersection of science, policy, aboriginal rights and public interest makes psychedelic medicines one of the most intriguing areas in modern medicine. This article explores the major trends and developments in the field of psychedelics, focusing on the legal landscape, market evolution, therapeutic research, and future possibilities.

The Legal Landscape of Psychedelics in 2024

The regulation of psychedelic substances remains one of the most complex aspects of this burgeoning field. In Canada, the Controlled Drugs and Substances Act (CDSA) continues to classify psychedelics like psilocybin, MDMA, and LSD as controlled substances, prohibiting their possession, distribution, and production except under specific exemptions.

Health Canada's regulatory frameworks allow access to psychedelics primarily through two pathways: the Special Access Program (SAP) and Section 56 exemptions. While these programmes offer limited compassionate use for individuals with life-threatening conditions and facilitate research, the overall accessibility of psychedelics in Canada remains restrictive. Comparisons to cannabis legalisation frequently surface, with many observers wondering if psychedelics might follow a similar path.

The focus in Canada remains predominantly on medical and research use. Public support for recreational psychedelics is in its early stages, and any move towards decriminalisation or legalisation is expected to be slow and cautious. The key regulatory bodies involved include Health Canada, provincial health authorities, and law enforcement, with each playing a role in ensuring compliance with current laws.

Cross-jurisdictional influence

One of the most notable factors influencing Canada's psychedelic regulatory framework is the progress made in other jurisdictions, particularly the United States. Oregon, for instance, became the first US state to create a legal, therapeutic psilocybin programme, while Colorado is moving towards establishing its own medical psychedelics access system. These developments are closely watched by Canadian regulators, as the outcomes from these US programmes could inform future legislative reform in Canada.

International progress can also drive change, with other countries exploring the medical benefits of psychedelics, such as Australia's decision to allow MDMA and psilocybin for therapeutic use. These global trends may help to normalise the conversation around psychedelics and pressure Canadian regulators to reassess their stance.

The Psychedelic Medicine Market: A Snapshot

Although the psychedelic medicine market in Canada is still in its infancy, there has been rapid growth in certain sectors. While access is currently limited to medical and clinical trial contexts, the underground market is thriving in cities like Vancouver, Toronto, and Montreal, where illegal psilocybin dispensaries operate with varying degrees of law enforcement tolerance. Further, the opioid and fentanyl epidemic continues to devastate communities across Canada, prompt-

ing a growing interest in psychedelic therapies as potential treatments for addiction and mental health disorders.

Medical market

The legal psychedelic market in Canada is driven by medical and therapeutic use, with clinical trials playing a key role. Research into the therapeutic benefits of psychedelics for treating mental health conditions such as PTSD, depression, and anxiety is gaining traction. Health Canada continues to approve clinical trials, and a growing number of patients have been granted access to psilocybin and MDMA through Section 56 exemptions or the SAP.

However, the hurdles to accessing these treatments remain significant. The SAP, while offering a legal pathway, is highly restrictive, with a complex application process and limited approvals. Similarly, clinical trials are available to only a small segment of the population, leaving many Canadians without viable legal access to these therapies.

Underground and grey market

Alongside the medical market, an underground market for psychedelics is expanding rapidly. Psilocybin dispensaries, modelled after the early cannabis dispensaries in Canada, are increasingly common in urban centres. These dispensaries sell a range of psychedelic products, from mushrooms to microdosing kits, often operating openly despite their illegality.

The response from law enforcement has been inconsistent. In Vancouver, for example, police have largely turned a blind eye to these operations, while in other cities like Toronto, there have been raids and seizures of psychedelic products. This fragmented enforcement approach creates a grey area for consumers and businesses alike.

Corporate and investment interest

The potential for psychedelic medicines has attracted significant interest from investors and corporations, particularly those involved in biotechnology and mental health treatment. While many early-stage companies have focused on research and development, there is growing interest in the commercial potential of psychedelics, especially if the regulatory environment shifts in favour of broader medical or recreational use.

However, this enthusiasm has been tempered by the challenges faced by some prominent psychedelic companies. For example, in 2023, Field Trip Health, a major player in the psychedelic therapy space, collapsed after burning through nearly CAD100 million in investment. Similarly, other companies have faced financial difficulties, leading to layoffs and business closures. These setbacks are often attributed to the slow pace of legalisation and the speculative nature of investments in the psychedelic sector.

Therapeutic Potential of Psychedelics: Research and Clinical Trials

One of the most promising areas of development in the field of psychedelics is the growing body of research demonstrating their potential therapeutic benefits. In 2024, clinical trials continue to investigate the efficacy of psychedelics like psilocybin and MDMA in treating a variety of mental health conditions, including treatment-resistant depression, anxiety, PTSD, and addiction.

Psilocybin for mental health

Psilocybin, the active ingredient in “magic mushrooms”, has been the focus of numerous clinical trials. Studies have shown that it can help alleviate symptoms of depression, especially in patients who have not responded to traditional treatments. Psilocybin has also demon-

strated promise in reducing anxiety, particularly in patients facing terminal illnesses. The effects are often described as profound, leading to improved mental well-being and a greater sense of peace.

MDMA for PTSD

MDMA, commonly known as ecstasy, has been designated as a breakthrough therapy by the U.S. Food and Drug Administration (FDA) for its potential in treating PTSD. Studies have shown that MDMA-assisted psychotherapy can significantly reduce symptoms of PTSD, offering hope to individuals who have long struggled with the condition. Clinical trials are underway in Canada, with many patients accessing MDMA through Health Canada's exemption process.

Ketamine and other psychedelics

Although ketamine has been legal for medical use in Canada for some time, its role in treating mental health conditions is gaining increased attention. Ketamine-assisted therapy is offered in specialised clinics across the country for conditions like depression and anxiety. Other psychedelics, including LSD and DMT, are also being researched, though they remain more tightly controlled under Canadian law.

Legal and Ethical Challenges in the Psychedelic Industry

As the psychedelic industry develops, it faces numerous legal and ethical challenges that companies, healthcare providers, and regulators must navigate.

Legal risks for businesses

For companies operating in the psychedelic space, legal risks are substantial. While clinical research and medical applications are permitted under certain conditions, the vast majority of commercial activity surrounding psychedelics is illegal. This is particularly true for businesses operating in the underground market, where the risk of law enforcement actions, such as raids, asset seizures, and criminal charges, remains high.

Even for those operating within the legal framework, compliance with Health Canada's stringent regulations is essential. Failure to meet these standards can result in the suspension of clinical trials, fines, or damage to a company's reputation. Intellectual property rights present another challenge, as many psychedelic compounds, especially in their natural forms, cannot be patented, limiting the ability of companies to protect their innovations.

Ethical considerations

Beyond the legal risks, there are significant ethical considerations associated with the use of psychedelics in medical treatment. Ensuring patient safety, informed consent, and the proper administration of these substances is critical. Psychedelics can have powerful effects, and improper use or inadequate supervision could lead to adverse outcomes. Clinics offering psychedelic therapies must adhere to high ethical standards to avoid malpractice claims and ensure the safety and well-being of their patients.

Prospects for an Adult-Use Psychedelic Market

While medical use of psychedelics is steadily progressing, the idea of an adult-use, recreational market for psychedelics in Canada remains speculative at this point. However, as the landscape evolves, it is worth exploring what such a market might look like and the likelihood of its development.

Public sentiment and legal hurdles

Public sentiment towards recreational psychedelics is still developing, and there are significant hurdles to overcome before an adult-use market could be realised. Psychedelics carry a stigma tied to their countercultural associations in the 1960s and 1970s, and many still view them as risky or dangerous substances. Educating the public on the safety and potential benefits of psychedelics, particularly in low doses, would be a necessary first step toward legalising them for recreational use.

Regulatory bodies, such as Health Canada, have historically been cautious in their approach to drug policy reform. Any movement towards legalising psychedelics for recreational use would likely follow a long period of medical access and careful research, similar to the pathway taken for cannabis legalisation.

What an adult-use market could look like

If a recreational market were to develop in Canada, it would likely mirror the framework used for cannabis legalisation, with strict regulations governing the production, sale, and consumption of psychedelics. Licensed dispensaries could be established to sell psilocybin or other low-potency psychedelics, with age restrictions and limits on possession quantities.

Harm reduction measures would be central to any adult-use framework. Public education campaigns, training for dispensary staff, and restrictions on public consumption would be essential to ensure responsible use and minimise risks. Psychedelic retreats or controlled environments may also play a role, providing safe spaces for individuals to experience psychedelics under supervision.

Possible integration with Indigenous rights and traditional use

Any legislative route in Canada is likely to include consideration for the rights of Indigenous communities, especially regarding traditional use of psychedelics in ceremonial and healing contexts. Legislative frameworks could integrate the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) principles, allowing for regulated access to psychedelics for Indigenous practices and recognising the historical use of these substances. UNDRIP, adopted by the United Nations General Assembly in 2007, delineates both the individual and collective rights of Indigenous peoples on a global scale. These encompass various aspects, including culture, identity, religion, language, health, and education. Moreover, UNDRIP underscores the rights of Indigenous communities to preserve their traditions, customs, and the establishment of their own educational, media, and judicial institutions.

At the federal level in Canada, UNDRIP was given legislative recognition through the United Nations Declaration on the Rights of the Indigenous Peoples Act (2021). The primary objective of the federal act is to ensure that the laws of Canada are in harmony with UNDRIP. It requires the Canadian government to:

- take measures to ensure that federal laws are consistent with UNDRIP;
- prepare and implement an action plan to achieve the declaration's objectives; and
- submit annual reports to Parliament on progress toward these goals.

Before the federal government's adoption of Bill C-15, the province of British Columbia (BC) took the pioneering step of implementing UNDRIP at the provincial level. In 2019, BC introduced the Declaration on the Rights of Indigenous Peo-

ples Act (DRIPA) (2019). This provincial legislation recognises and affirms the application of UNDRIP in BC. DRIPA's provisions are similar to the federal act in terms of mandating action plans and ensuring that provincial laws are consistent with UNDRIP. It underscores the importance of consultation and collaboration with Indigenous communities in the province.

The adoption of UNDRIP into Canadian federal and provincial law reflects a commitment to rectify past injustices and promote a future built on mutual respect and partnership. The incorporation of UNDRIP principles in both federal and provincial legal landscapes reinforces the principle that the rights of Indigenous peoples are integral to Canada's legal and moral fabric.

The Royal Proclamation of 1763 forms the constitutional foundation for Indigenous treaties and legal rights. Section 35 of the Constitution Act, 1982, reinforces these principles, safeguarding Indigenous and treaty rights, in line with UNDRIP. These include the right to pre-colonisation practices related to farming, gathering, foraging, and seed propagation, underscoring the significance of sacred medicines (including psychedelic substances) in the context of Indigenous rights and access to traditional healing practices.

Conclusions

The psychedelic medicine landscape in 2024 reflects a rapidly evolving field, with significant strides in research, growing public interest, and cautious legal reform. While medical access to psychedelics remains limited, there is promising research demonstrating their therapeutic potential, particularly in treating mental health disorders like PTSD and depression. However, challenges persist, including regulatory hurdles, legal risks for businesses, and ethical concerns in patient care. As the underground market continues to thrive and global jurisdictions explore new policies, Canada's psychedelic future remains poised between cautious medical expansion and potential broader legalisation.

JAPAN

Law and Practice

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Contents

TMI Associates is one of Japan's largest law firms, with more than 700 attorneys, patent/trade mark agents, foreign lawyers, and other legal professionals - as well as 17 offices worldwide, including international branches in Asia, Europe and the USA, in addition to desks focusing on Brazil, India, Korea, Indonesia, Kenya, Malaysia, Mexico and the Philippines. TMI's renowned IP practice ranges from prosecutions and litigations to legal counselling. Other primary areas of practice include corporate and M&A, litigation and arbitration, banking and finance, antitrust and competition law, risk management, and labour and employment law. TMI supports clients across various industries, including life sciences. The firm's healthcare practice team has diverse experience, including scientific educational backgrounds as well as experience of working in the Ministry of Health Labour and Welfare and as practising medical doctors. Combined with TMI's global network, the team provides comprehensive legal services to healthcare businesses.

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1. Regulatory Overview

1.1 Primary Laws and Regulations

PMD Act

In Japan, the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the "PMD Act") serves as the primary law regulating pharmaceuticals, including their manufacturing, sales, business licences and product approvals, labelling, and advertisements. Psychedelic drugs are the drugs or substances that alter human body functions - specifically, brain activities. They also influence sensory perceptions, cognitions, consciousness and/or other mental capacities. Psychedelic drugs are, therefore, categorised and regulated under the PMD Act as pharmaceuticals.

General rules under PMD Act

For the marketing of pharmaceuticals, the relevant companies involved must obtain a business licence that corresponds to the product category and the form of the business operation (eg, manufacturing or sales). In order for a pharmaceutical product to enter the Japanese market, a Marketing Authorisation Holder has to obtain product approval (*Shonin*) for each specific item. Sales and advertisement of unauthorised pharmaceuticals are prohibited under the PMD Act and may result in the cancellation of business licences and/or criminal penalties. It is worth noting that, in Japan, any advertisements for prescription drugs that are directed at the general public are prohibited under the PMD Act, even when the product is approved for marketing authorisation.

Designated substances

In addition, under the PMD Act, substances that are highly likely to stimulate or depress the central nervous system or cause hallucinations (including actions that maintain or enhance such effects), and that may pose a health hazard when used in humans are defined as "designated substances". Note that narcotics, psychotropic drugs, opium and poppy straw, cannabis, and stimulants are separately defined and regulated by other specific laws, which are explained later in this subsection, and are excluded from the definition of designated substances.

Designated substances are designated by the Minister of Health, Labour and Welfare as either individual substances or as substance groups, using a broad designation for substances with

similar chemical structures. This list of substances is periodically updated.

Except for approved pharmaceutical uses or safe uses within the scope of the purposes (such as academic research) recognised under the PMD Act, it is prohibited under the PMD Act to manufacture, import, sell, transfer, possess, store, or display for the purpose of sale or transfer the designated substances or any products containing such substances. Violations of such prohibitions are subject to criminal penalties, including imprisonment.

Additional Regulations and Controlled Substances

The term "psychedelic drugs" is inclusive of common psychedelics such as LSD, MDMA, DMT, psilocybin, amphetamines and methamphetamines, but may also include substances such as ketamine, cannabis, and THC in a broader sense. In addition to the PMD Act, the above-mentioned psychedelic drugs are further regulated under specific laws for each relevant substance - namely, the following (each of which are further explained in the following paragraphs):

- the Narcotics and Psychotropic Drugs Control Act (the "NPC Act");
- the Opium Control Act;
- the Cannabis Control Act; and
- the Stimulants Control Act.

Together with the Narcotics Special Act, these control acts are sometimes collectively referred to as the "Five Drug Laws."

Please note that the definitions of "narcotics" and "psychotropic drugs" under Japanese law may not always align with international classifications.

NPC Act

Under the NPC Act, "narcotics" and "psychotropic drugs" are defined as substances listed in the respective schedules of the NPC Act, including substances that have similar abuse potential and harmful effects and are so designated by government ordinance.

Narcotics

Narcotics include substances such as ketamine, DMT, psilocybin, MDMA, mescaline, and LSD. The use of narcotics permitted under law is restricted to medical and academic research purposes. The handling of narcotics is strictly regulated by a licensing system.

Only those entities holding the following business licences - (i) Marketing Authorisation Holder Licence, (ii) Marketing Authorisation Holder Licence or Sales Licence, and (iii) Marketing Authorisation Holder Licence or Manufacturer Licence - under the PMD Act are eligible for licences to, respectively, (i) import, (ii) export, and (iii) manufacture narcotics under the NPC Act. Pharmacies must have a Narcotics Retailers Licence to deliver prescribed narcotics to patients. Those who sell narcotics to narcotics retailers, medical facilities, or research facilities must have a Narcotics Wholesaler Licence.

Only physicians, dentists and veterinarians with a Narcotics Use Licence are permitted to administer, prescribe and dispense narcotics. When there are more than two such doctors in one facility, it must have a licensed Narcotics Manager to ensure proper handlings and management of narcotics in that medical facility. Researchers also require a licence to conduct narcotics research.

Narcotics business licence holders are subject to strict obligations regarding the handling of

narcotics, such as keeping records of quantities and dates of dispensing, as well as administration to the patients and regular reporting to the authority.

Criminal penalties, including imprisonment, are provided under the NPC Act for violations of these regulations.

Psychotropic drugs

Psychotropic drugs are subject to similar regulations under the licensing system. Violation of these regulations may result in criminal penalties.

Further, psychotropic drugs are classified into three categories based on their abuse risk: Category I (eg, methylphenidate), Category II (eg, flunitrazepam, pentazocine), and Category III (eg, triazolam, brotizolam). Import and export of Category I psychotropic drugs require approval from the Minister of Health, Labour and Welfare, whereas Category II drugs require notification to the Minister of Health, Labour and Welfare for each import/export transaction.

Raw materials of narcotics and/or psychotropic drugs

Businesses importing, exporting and/or selling raw materials for narcotics and/or psychotropic drugs require submission of notification to the authority. Such notifications are also required when someone not holding a business licence imports or exports the raw materials.

Opium Control Act

The Opium Control Act defines "opium" as the coagulated liquid juice of poppies and processed products thereof (excluding products processed as pharmaceutical products).

Under the Opium Control Act, the authority to import and export opium, purchase opium from poppy cultivators, and sell opium to licensed narcotics manufacturers or licensed narcotics research institutions is exclusively vested in the Japanese government.

Cannabis Control Act

The cannabis plant (except the portions of grown stalks and seeds), products made therefrom, and resin produced from grown stalks of the cannabis plant fall under the definition of "cannabis" and are subject to regulation under the Cannabis Control Act. By way of example, a cannabidiol (CBD) syrup product would fall under the definition of cannabis and be subject to regulation under the Cannabis Control Act if it is made from portion of cannabis plant other than grown stalks or seeds.

The law limits the lawful uses of cannabis to academic research and the collection of its fiber and seeds, and requires the handlings of cannabis to be licensed. Violations of the Cannabis Control Act are subject to criminal penalties, including imprisonment. Only licensed cannabis handlers (namely, cannabis cultivators and cannabis researchers) are permitted to cultivate, possess and transfer cannabis. Importation of cannabis is restricted to cannabis researchers only, who may import it solely for research purposes with approval from the Minister of Health, Labour and Welfare.

Major amendment due to come into effect

It is very important to note that a major amendment to the Cannabis Control Act was enacted in December 2023 and is due to come into effect on 12 December 2024, changing its name to the "Act Concerning Regulation of Cannabis Plant Cultivation".

The main topics in the amendment to note include the following.

- The scope of definition of "cannabis" will be revised to the following: cannabis plant (except the portions of grown stalks and seeds) and products made therefrom (excluding those not having the form of the plant). As such, for example, a CBD syrup product (whether from the cannabis plant or chemically synthesised) would not fall under the definition of cannabis - given that it no longer has the form of the plant.
- Cannabis will be categorised and regulated as a narcotic under the NPC Act.
- THC, known as the toxic component of the cannabis plant, will also be defined as a narcotic. That being said, even if an item contains THC (whether from the cannabis plant or chemically synthesised), if the percentage of THC is below the maximum limits set forth by a cabinet order and the item does not contain other narcotics, it shall be exempt from the definition of narcotics.
- Pharmaceutical medicines made from the cannabis plant will be legal, subject to the regulations under the NPC Act. Prior to the amendment, they were banned entirely.
- Inappropriate "use" has now come into the scope of prohibition and criminal penalties, as opposed to regulation before the amendment whereby "use" of cannabis was not punishable.

Stimulants Control Act

Under the Stimulants Control Act, "stimulants" are defined as:

- phenylaminopropane (known as amphetamine), phenylmethylaminopropane (known as methamphetamine) and their salts;
- substances that have a stimulating effect similar to the foregoing and are so designated by a cabinet order; and
- substances containing any of the foregoing.

The Stimulant Control Act limits the legal use of stimulants to medical and academic research purposes and requires designations by the authority for handling the stimulants. Violations of the Stimulants Control Act are subject to criminal penalties, including imprisonment.

The Stimulants Control Act stipulates that no person may import or export stimulants at all.

Raw materials for stimulants (substances that are listed and defined in the attachment to the Stimulants Control Act) can be imported and exported - albeit only with Stimulants Raw Materials Importer/Exporter designations as applicable.

Only the entities holding both a Marketing Authorisation Holder Licence and a Manufacturer Licence under the PMD Act are eligible to be designated as stimulants manufacturers under the Stimulants Control Act.

Facilities that can be designated as stimulants dispensing facilities by the authority are limited to psychiatric hospitals and other medical institutions that require stimulants for medical treatment.

Only researchers who are acknowledged to have sufficient knowledge of stimulants and are proven to need to use stimulants in their research can be designated as stimulants researchers.

These designated individuals and entities are permitted to handle stimulants accordingly during the effective period of their designations only

(ie, from the date of designation until December 31 of the following year). They are also subject to strict obligations, including maintaining records of stimulant use, regular reporting to the authority, and ensuring stringent storage and management of the stimulants.

Narcotics Special Act

In addition to the above-mentioned control acts, the Act on Special Measures Concerning the Narcotics and Psychotropic Drugs Control Act, etc. for Aiming the Prevention through International Co-operation of Acts Aiding Fraudulent Activities Related to Controlled Substances (the "Narcotics Special Act") provides further rules regarding criminal penalties for drug crimes involving narcotics, psychotropic drugs, opium and poppy straw, cannabis, and stimulants (collectively define as "controlled substances" under the Narcotics Special Acts. Examples include confiscations and restraining orders, as well as deprivation of drug crime proceeds.

Other laws

The Customs Act also prohibits the unlawful import and export of controlled substances.

In some cases, in addition to the above-mentioned laws and regulations, local governments may have additional municipal regulations on those drugs that are deemed to have the same effects on the human mind as stimulants or cannabis (eg, excitement, hallucination, intoxication, or other similar effects) and where the abuse of such substance would cause damage to human health.

Options for Early Access, Compassionate Use, or Use in Other Limited or Extenuating Circumstances

There are no expedited or expanded routes (eg, early access or compassionate use systems) that are specifically designed for the introduction of psychedelic medicines into the market. However, there are certain systems that are generally applicable to pharmaceuticals, and psychedelic medicines may also be able to utilise these routes if they meet the requirements.

Some pharmaceuticals, based on factors such as demand for their intended use, receive special designations under pharmaceuticals policy to promote their development. These designation categories include:

- orphan drugs;
- innovative pharmaceuticals; and
- pharmaceuticals for specific uses.

If a drug receives any of these designations, it becomes eligible for preferential treatment, which may include priority reviews and accelerated approval processes.

Orphan drugs are designated based on the rarity of the target patient population, the seriousness of the condition, the high medical need (eg, the availability of alternative treatments and reliability in the effectiveness and safety of the drug), and the rationality and feasibility of the development plan.

Innovative pharmaceuticals must demonstrate innovativeness in their pharmaceutical mechanism of action, target serious or life-threatening diseases for which there is no curative treatment, show high effectiveness, and be developed in Japan ahead of the rest of the world.

Pharmaceuticals for specific uses are designated based on the seriousness of the disease and require that the treatment has been established as the standard international therapy. This desig-

nation is limited to drugs for paediatric use or for diseases caused by drug-resistant pathogens.

Priority review might still be granted, even outside these categories, based on the severity of the target disease and whether the drug demonstrates superior effectiveness or safety compared to existing treatments.

Expanded clinical trials

The "expanded clinical trial" is a system in Japan that was introduced in 2016 and is comparable to a compassionate use system. It is a system in which unapproved drugs or medical devices are made available, from a humanitarian perspective, to patients who do not meet the criteria for participation in clinical trials for the treatment of life-threatening diseases for which there are no effective existing treatments. The expanded clinical trial is not a trial performed via an independent route on its own but, rather, is conducted within the scope of the existing clinical trial system. What makes it different from typical clinical trials is that:

- when the sponsor does not start an expanded clinical trial, the patient/doctor has the option to ask the Ministry of Health, Labour and Welfare to issue a request to the sponsor to re-consider conducting an expanded clinical trial; and
- the patient in some cases might bear part of the cost based on informed consent.

The decision as to whether the expanded clinical trial shall be performed is up to the sponsor and is not mandatory.

The requirements for establishing an expanded clinical trial are that:

- the targeted disease is serious and has a fatal influence;
- the product or indication is unauthorised and no effective alternative treatment exists;
- the clinical trial (the "Main Trial") for the substance is already running and is in the final stage (and after enrolment) or has been completed; and
- no negative impact on the performance of the Main Trial or the marketing implementation of the product will be caused.

1.2 Regulatory Bodies

Ministry of Health, Labour and Welfare and Its Relevant Regulatory Bodies

The Ministry of Health, Labour and Welfare is the authority responsible for overseeing the PMD Act, which covers a wide range of general regulations concerning pharmaceuticals. These include approval processes, product authorisations, and labelling and advertising regulations, as well as involvement in the enforcement of illegal or unauthorised drug control.

The Pharmaceuticals and Medical Devices Agency (PMDA) is a governmental agency supporting the Ministry of Health, Labour and Welfare. This includes reviewing the marketing approval process of pharmaceutical products.

Narcotics Control Officers, who are part of the Narcotics Control Department in regional health bureaus (which are local branches of the Ministry of Health, Labour and Welfare), have the authority to enforce arcotics control measures. These officers also possess the powers of special judicial police officers under the Criminal Procedure Code when it comes to narcotics enforcement.

Others

The police also exercise their authority in cracking down on illegal drugs.

The import and export of illegal drugs constitute violations of the Customs Act. Customs officials have the authority under this law to inspect, seize, and take other actions against such cargo.

1.3 Self-Regulatory Authorities

There are no specific self-regulatory authorities that govern the psychedelic medicine industry or psychedelic trials in Japan.

1.4 Existing Market

Narcotics, Psychotropic Drugs, and Stimulants

Under the strict regulatory framework of the NPC Act, medical narcotics such as opioid drugs are sold on the Japanese pharmaceuticals market. Narcotic analgesics, such as morphine and fentanyl, are essential for pain management in cancer patients and end-of-life care. The need for cancer treatment and chronic pain management is increasing because of Japan's ageing society and, as such, the demand for opioid analgesics is substantial in Japan.

Psychotropic drugs, including antidepressants, anti-anxiety medications and antipsychotics, are commonly used as treatments for mental health conditions and neurological disorders.

Stimulants are also legally marketed for medical use. There is, for example, a methamphetamine-based prescription drug for treating narcolepsy, depression, etc.

All of the foregoing are marketed and regulated as prescription drugs.

As an additional information, according to a publicly available database, some clinical studies to access the safety and efficacy of psychedelic drugs for treating depression are underway. For further details, please see "Clinical studies of psychedelic drugs for treating depression" in the Japanese Trends and Developments chapter of this guide.

Cannabis-Based Medicines

However, cannabis-based medicines have not yet been marketed because the Cannabis Control Act – prior to the recent amendment – entirely prohibited such substances, even as prescription drugs.

Earlier in 2024, it was reported that the cannabis-derived anti-epileptic drug Epidiolex (currently pending approval) was designated as an orphan drug. This marks the first case of a cannabis-derived pharmaceutical being designated as an orphan drug in Japan. Thanks to the recent amendment to the Cannabis Control Act that relaxed the prohibition for medical use, once the product obtains marketing approval, this medication can be legally sold and used as a prescription drug in Japan.

Limited Market Scope

As such, there is a limited existing market for psychedelics. However, in Japan, there is currently no therapeutic use of psychedelic drugs outside prescription drug use.

1.5 Challenges Facing Market Participants

As explained in **1.4 Existing Market**, psychedelic drugs can be legally marketed and used in Japan as pharmaceuticals (specifically, as narcotics, psychotropic drugs, etc.) and there is actually demand for such pharmaceutical products in the market. However, the products are heavily regulated.

Notably, in order to manufacture and sell psychedelic drugs as pharmaceutical products in Japan, a relevant business licence must be

obtained and a marketing authorisation for each product must be obtained in order for the product to be sold. Additionally, strict controls are implemented under the control acts mentioned **1.1 Primary Laws and Regulations** (eg, the NPC Act), which carry the risk of criminal penalties for violations. These may be significant challenges that market participants would need to face in terms of potential legal risks.

In addition, coupled with Japanese society's conservative views towards controlled drugs, the reputational risk for companies in the event of legal violations or even the suspicion thereof regarding controlled substances (including psychedelic medicines) would be higher than that regarding the usual pharmaceuticals.

2. Cross-Jurisdictional Matters

2.1 Common Cross-Jurisdictional Issues

When considering activities or business operations related to controlled substances, one question that may arise concerning cross-jurisdictional issues would be the applicability of criminal penalties stipulated by Japanese law. Specifically, a discussion on the applicability of Japanese law may arise regarding whether certain activities or business operations related to controlled substances that may be illegal in Japan but legal in foreign countries are lawful and whether criminal penalties under the relevant Japanese laws may apply.

According to the Penal Code of Japan (Article 2), which stipulates that for some crimes "the following are also applicable to any and all persons who committed the crimes outside Japan" - meaning certain provisions extend to crimes committed outside the country. Article 2 is incorporated by citation into the control acts mentioned in **1.1 Primary Laws and Regulations** with regard to several criminal penalties for the acts of possession, use, transfer and import/export of controlled substances (or the financing of such activities).

As a result, at least in theory, certain scopes of handling controlled substances are unlawful under Japanese law – even if it is legal in other countries - and could technically be subject to criminal penalties under the relevant control acts in Japan. However, the possibility of the relevant authority actually enforcing such penalties remains a separate issue.

This issue would be particularly relevant for international corporations with operations in Japan. Companies or their employees may face legal risks when they engage in certain activities abroad - for example, the possession or use of controlled substances, or business operations relevant to controlled substances or investment in such businesses. It is therefore advisable for companies to be aware of the potential for Japanese law to apply to actions taken outside Japan, even if those actions are lawful in the foreign country, and to review the legal risk in this regard in advance.

2.2 How Access Is Affected by Foreign Law and Regulation

The legal regulations abroad and legal accessibility within Japan are entirely independent of one another. Foreign laws and regulations generally do not influence access to psychedelic drugs in Japan.

In order to market psychedelic medicines in Japan, an approval under the PMD Act is required. Any substances or actions deemed legal overseas do not necessarily make them lawful within Japan.

Generally speaking, it is possible that broader trends in legal reform abroad indirectly impact regulatory relaxation in Japan. However, the social and legal climate in Japan remains notably conservative, particularly with regard to controlled substances such as psychedelic drugs. Thus, even if certain substances are legalised overseas, there is no particular indication that Japan will follow the trend towards legal relaxation.

One potential scenario is that, should the usefulness and safety of a particular drug become firmly established abroad in the future, this could serve as part of the scientific evidence used when applying for marketing approval in Japan. Additionally, such developments might eventually lead to regulatory easing for medical use of the drug in Japan. Nevertheless, any such influence from overseas will remain indirect.

3. Legal and Regulatory Developments

3.1 Access to Psychedelic Medicines Today

As explained in **1.4 Existing Market**, psychedelic medicines can only be legally marketed in Japan as prescription drugs, which are subject to regulations under the PMD Act (as explained in **1.1 Primary Laws and Regulations**). Additionally, they must be controlled under the strict regulations under the NPC Act or other control acts as applicable. Those rigid regulations reflect the Japanese government's strict attitudes towards drugs and the regulation thereof.

This field is touched on by the regulators' agenda, for example, in the recent amendment to the Cannabis Control Act (see **1.1 Primary Laws and Regulations**). This amendment newly legalised pharmaceuticals made from cannabis. However, this was aimed at improving the availability for patients, and relaxing the regulations was not the goal of the amendment.

Given the Japanese government's strong stance and strict policies against drug abuse, as well as the generally conservative, non-accepting attitude of Japanese society towards controlled substances, there is little sign of the mood or discussion shifting in favour of further relaxing regulations on controlled substances (including psychedelics).

3.2 Legislative Routes to Wider Access

The general process of legislation, including the enactment of amendments, is as follows.

- A bill is submitted to the Diet during its session, either by members of Congress (in the Upper House or the Lower House) or by the Cabinet of Japan. In the case of a bill submitted by the Cabinet of Japan, the draft is prepared by the relevant Ministries overseeing the subject matter of the legislation.
- Once submitted, the bill is first deliberated in the congressional house in which it was submitted. After going through primary review by the relevant committee in that congressional house, it is debated in a plenary session in the house to be voted on. Then, the bill is passed to the other house and goes through the same review and deliberation process. When both houses pass the bill in agreement, it is enacted into law.
- After its enactment, the law is promulgated and subsequently enforced.

Throughout this process, lobbying activities by the relevant industry groups, patient associations and other stakeholders may also influence lawmakers and bureaucrats. A surge in public opin-

ion or social climate can also serve as motivation for law-makers or the Cabinet of Japan to draft legislation. By way of example, one of the driving motivations behind the recent amendment to the Cannabis Control Act was the demand from patients for the legalisation of cannabis-based pharmaceuticals that had already been used in several foreign countries for medical treatment purposes such as intractable epilepsy and yet were prohibited and unavailable in Japan.

3.3 Adult-Use Markets

Legalisation of adult use (ie, non-medical, recreational use) in Japan is extremely unlikely, considering the circumstances mentioned in **3.1 Access to Psychedelic Medicines Today**. With the recent trend for legalisation of some controlled substances overseas, the Japanese government is getting more cautious regarding the spread of inappropriate drug use introduced from abroad and change cannot be expected to take place anytime soon.

Trends and Developments

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TMI Associates is one of Japan's largest law firms, with more than 700 attorneys, patent/trade mark agents, foreign lawyers, and other legal professionals - as well as 17 offices worldwide, including international branches in Asia, Europe and the USA, in addition to desks focusing on Brazil, India, Korea, Indonesia, Kenya, Malaysia, Mexico and the Philippines. TMI's renowned IP practice ranges from prosecutions and litigations to legal counselling. Other primary areas of practice include corporate and M&A, litigation and arbitration, banking and finance, antitrust and competition law, risk management, and labour and employment law. TMI supports clients across various industries, including life sciences. The firm's healthcare practice team has diverse experience, including scientific educational backgrounds as well as experience of working in the Ministry of Health Labour and Welfare and as practising medical doctors. Combined with TMI's global network, the team provides comprehensive legal services to healthcare businesses.

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Overview of Legal Framework in Japan

The term "psychedelic drug" lacks a legal definition but in general refers to substances that affect the central nervous system, influencing perception, thoughts, cognition, and sensory experiences. These effects often include altered states of consciousness, hallucinations, and changes in mood.

In Japan, such substances are defined and regulated as pharmaceuticals - more specifically, prescription drugs - under the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices (the "PMD Act"). In addition to the rules generally applicable to pharmaceuticals, the PMD Act specifically defines substances that are highly likely to stimulate or depress the central nervous system or cause hallucinations (including actions that maintain or enhance such effects) and that may pose a health hazard when used in humans as "designated substances". Designated substances are subject to strict regulatory controls.

In addition to the PMD Act, Japan enforces strict control laws for narcotics, psychotropic drugs, opium, cannabis, and stimulants. These laws include rigorous licensing requirements, coupled with severe criminal penalties for any unauthorised handlings of such drugs.

Depending on their chemical composition, psychedelic drugs may fall under either of these regulatory frameworks. As a consequence of these layered regulations, the market opportunity for psychedelic drugs in Japan is significantly constrained and their use is largely confined to prescription medications in clinical settings.

Although more detailed information on specific regulations can be found in the Japan Law and Practice chapter of this guide, this article will focus more on current trends and developments concerning psychedelic drugs in Japan, including the social factors behind the strict legal controls and recent noteworthy amendments to the relevant control laws.

Social Climate and Cultural Context in Japan Regarding Use of Controlled Drugs

To understand Japan's strict legal stance on psychedelic drugs and other controlled substances, it is essential to examine the broader social and cultural context. Japan has long maintained a conservative approach to drug use. Drug use is often viewed with strong moral condemnation

and there is a social stigma attached to the inappropriate use of controlled substances.

According to a slightly dated but still relevant statistic from a 2017 survey by Japan's Ministry of Health, Labour and Welfare, the lifetime usage rates of controlled substances among Japanese individuals aged 15 to 64 were: 1.4% for cannabis, 0.5% for stimulants, 0.3% for cocaine, and 0.2% for other synthetic drugs. These figures are significantly lower than in many other countries.

Whether this is a cause or result of the conservative social view on drug use in the Japanese society is debatable, but this might reflect the societal attitude whereby many people refrain from using controlled substances not only because of the legal repercussions but also as a consequence of the cultural taboo surrounding drug use.

Government Action on Drug Abuse

Despite low drug usage numbers and rates, drug offences - particularly among the younger population - are on the rise, and the Japanese government has recognised this as a growing problem. The Japanese government is consistently sending strong messages to the public through multiple channels that drug abuse will not be tolerated.

One such initiative addressing this issue is the establishment of the Drug Abuse Prevention Promotion Conference, chaired by the Minister of Health, Labour and Welfare and organised under the Cabinet of Japan. This conference regularly proposes and renews a "Five-Year Strategy for Drug Abuse Prevention", which outlines five key goals as the government's strategic objectives during the following five-year period. The conference publishes an annual follow-up report on its progress.

The five goals for the current Five-Year Strategy for Drug Abuse Prevention include:

- raising public awareness, particularly among youth, to prevent drug abuse through education and outreach;
- providing appropriate treatment for drug abusers and supporting their reintegration into society to prevent relapse;
- cracking down on domestic and international drug trafficking organisations, with a particular focus on cannabis and other abused substances, while promptly responding to the diversification of illicit drugs;
- strengthening border controls to prevent drug smuggling; and
- promoting international collaboration to prevent drug abuse as a member of the global community.

Japan's Response to Global Trends

In recent years, there has been a growing trend in some countries towards relaxing regulations on certain drugs. By way of example, several nations have moved to decriminalise or legalise cannabis for recreational use. However, Japan has been largely resistant to these changes.

In the most recent Five-Year Strategy for Drug Abuse Prevention (formulated in August 2023), the Japanese government emphasised maintaining a strict stance on controlled substances, despite global trends towards relaxing regulations. The strategy acknowledges the shift in some countries toward legalising cannabis for recreational use by explicitly mentioning such fact. However, the Japanese government views Japan's exceptionally low lifetime drug use rate - in comparison to other nations - as a success of its current drug prevention policies and states that Japan's strict drug policies should continue to ensure public safety and security.

Reasons Behind Major Amendment of Cannabis Control Act

One of the major recent amendments to the laws regulating controlled substances is the Cannabis Control Act. Under the Cannabis Control Act prior to the amendment, cannabis-derived pharmaceuticals were entirely prohibited. However, following its passage by the National Congress in December 2023, the revised Cannabis Control Act is set to come into effect on 12 December 2024 and relax the ban on cannabis-derived pharmaceuticals.

One motivation behind the amendment was the growing demand for the legalisation of cannabis-derived pharmaceuticals within Japan. Some cannabis-derived medicines are already in use in many Western countries, yet they have been completely unavailable to the patients in Japan prior to this amendment.

Even though the legalisation of these pharmaceuticals may appear to be a form of deregulation, it would not be appropriate to say that deregulation was the main focus behind this amendment. Rather, a key point of this revision was the reformation of the regulatory frameworks to ensure proper control over cannabis-related substances and strict prevention of drug abuse, while reasonably legalising the necessary medical use of cannabis-derived pharmaceuticals. Here are the details.

The government outlined the following key objectives for the purpose of the legal amendment:

- the establishment of provisions to allow for the use of pharmaceuticals derived from cannabis plants;
- the establishment of provisions related to the application of penalties for the use of cannabis; and
- the revision of regulations concerning the cultivation of cannabis plants, among other measures.

The amendment will take effect shortly after 12 December 2024 and includes, among other things, the following revisions.

- The definition of "cannabis" has been revised. The scope of cannabis under the pre-amendment Cannabis Control Act was as follows: the cannabis plant (except the portions of grown stalks and seeds), products made therefrom, and resin produced from grown stalks of the cannabis plant. Following the amendment, cannabis will be defined as: the cannabis plant (except the portions of grown stalks and seeds) and products made therefrom (excluding those not having the form of the plant). By way of example, a cannabidiol (CBD) syrup product would fall under cannabis prior to the amendment if it is made from a portion of the cannabis plant other than grown stalks or seeds, whereas following the amendment it will fall outside the scope of cannabis – whether it is from the cannabis plant or chemically synthesised – because it no longer has the form of the plant.
- Cannabis will be categorised as and regulated as a narcotic under the Narcotics and Psychotropic Drugs Control Act (the "NPC Act").
- THC, known as the toxic component of the cannabis plant, will also be defined as a narcotic. That said, even if an item contains THC (whether from the cannabis plant or chemically synthesised), if the percentage of THC is below the maximum limits set forth by a cabinet order and the item does not contain

other narcotics, it shall be exempt from the definition of narcotics.

Before the amendment, the regulation of CBD - which is not a narcotic component - was unclear and the regulation of toxic components such as THC that remain in products derived from the cannabis plant was not clearly addressed under the Cannabis Control Act. After the amendment, the regulation of these substances is now delegated to the NPC Act.

- Going forwards, medicines made from the cannabis plant can be legal as pharmaceutical products in the same manner as narcotic medicines, subject to the applicable regulations under the NPC Act.
- Inappropriate "use" has now come into the scope of prohibition and criminal penalties, as opposed to regulation before the amendment whereby "use" of cannabis was not punishable.

To elaborate on the final point, under the Cannabis Control Act prior to the amendment, criminal penalties were imposed for activities such as importing, cultivating, possessing or transferring cannabis, but there were no penalties for its use. This is said to have been derived from the existing concerns at the time the law was first enacted, which considered the potential for unintentional use by farmers cultivating cannabis plants during harvest (such as naturally inhaling cannabis components dispersed in the air). However, it has since been revealed that there is little scientific basis for such concerns.

Additionally, with the number of individuals arrested for cannabis-related offences - particularly younger people - rising in recent years, police investigations have shown that many of those arrested were aware that cannabis use itself was not punishable by law. This awareness likely contributed to the increased abuse of cannabis. As a result, the opinion emerged that - in order to prevent drug abuse - the act of using cannabis should also be subject to punishment.

Based on these discussions and opinions, in the amendment, the act of cannabis use per se has been criminalised.

For reference, the timeline of this Cannabis Control Act amendment process was as follows. In early 2021, the Ministry of Health, Labour and Welfare set up a review panel to discuss policies regarding drug issues including cannabis. The following year, in 2022, a committee established by the Ministry of Health, Labour and Welfare presented proposals for the direction of the revisions of the Act. The bill was then submitted to the National Congress in October 2023, passed by both the Lower and Upper Houses, and enacted in December 2023.

Recent Moves in Medical Cannabis Market

Following the revision of the Cannabis Control Act, some companies have begun to explore opportunities in the medical cannabis business.

Recently, it was reported that Epidiolex - a pharmaceutical product containing CBD derived from cannabis - has received a designation as an "orphan drug". This marks the first time in Japan that a cannabis-derived pharmaceutical has been designated as an orphan drug. Moreover, once approved under the newly amended law, this will be the first cannabis-derived pharmaceutical.

Thanks to this legal revision, cannabis-derived medications can now be marketed as pharmaceuticals, which opens up a legal pathway for their use in the healthcare industry. This devel-

opment will potentially impact the business opportunities in this field.

However, whether or how soon this will lead to a major business trend remains uncertain. Despite the theoretical legality of investing or engaging in the medical cannabis business, some companies are still feeling hesitant about getting themselves involved, owing to concerns about the reputational risks that could arise from stakeholders. Even though the business and the products may be legal, many companies are behaving conservatively, taking potential reputational risks into account.

Clinical studies of psychedelic drugs for treating depression

According to a publicly available database, some clinical studies to determine the safety and efficacy of typical psychedelic drugs – for example, psilocybin and ketamine (both of which are regulated as narcotics) – for treating depression are underway. These clinical studies are medical research on human patients, aimed at improving methods for treating depression. Unlike clinical trials conducted for the purposes of gaining marketing approval of a pharmaceutical product, these clinical studies are not directly linked to drug commercialisation. However, the accumulation of such studies may help establish scientific evidence to support the clinical potential of psychedelic drugs.

Concluding Remarks

In Japan, psychedelic drugs - like other controlled substances - are subject to stringent regulation under the PMD Act and other control laws. The country's conservative social climate, combined with a robust legal framework, has resulted in exceptionally low rates of drug use compared to global averages.

Given the present government's attitude, which recognises the need to address rising drug offences (particularly among young people) and remain committed to its strict drug policies, it is difficult to imagine that Japan will follow global trends towards the deregulation of controlled substances - despite the recent shifts towards more lenient drug laws in other parts of the world.

Having said that, if clear medical and scientific evidence for a controlled substance in the treatment of a disease is found overseas, that could promote drug development in Japan or lead to the deregulatory legislative changes necessary to make such controlled substance available to patients in Japan as a prescription drug. As long as there is medical demand and the drugs follow the appropriate pharmaceuticals approval process and obtain the necessary licences, psychedelic medicines can be marketed in Japan.

UK

Law and Practice

Contributed by:
Elliott Rolfe and Harry Lancaster
Mackrell.Solicitors

Contents

Mackrell.Solicitors is an award-winning, full-service law firm, which has provided high-quality legal advice and services since 1845. As a founder of Mackrell International, the 35-year-old global network comprising 90 firms across 60 countries, Mackrell.Solicitors can offer immediate international legal advice and assistance in any jurisdiction worldwide from its London headquarters and Birmingham office. The UK's first dedicated psychoactive medicines legal team was set up by the firm five years ago to provide regulatory advice and services for the psychedelic medicines, medicinal cannabis and cannabinoid industries. The team has market-leading sector knowledge and is at the cutting edge of the current EU and UK regulatory regimes. It deals with the whole life cycle of psychedelic and medical cannabis businesses from start-up to exit, advising clinics, charities, clinical researchers and international wellness organisations, as well as distributors and other parts of the supply chain. Mackrell.Solicitors' practice focuses on regulatory advice and solutions, licensing and agreements, import, and product compliance, promotion and governance.

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1. Regulatory Overview

1.1 Primary Laws and Regulations

In the UK, psychedelic medicine refers to a wide range of medicines that have a number of common elements – they are controlled substances in law, they have particularly psychoactive effects, they usually (but not always) rely on activation of the 5HT2A receptor as the primary mechanism of therapeutic action, and they commonly (but not always) have a botanical origin. The most studied psychedelic medicines include:

- psilocybin – the most active compound in so-called magic mushrooms;
- dimethyltryptamine (DMT) – the most active compound in the Amazonian ayahuasca brew);
- 3,4-Methylenedioxymethamphetamine (MDMA) – historically referred to as "Ecstasy";
- lysergic acid diethylamide (LSD) – originally derived from ergot, a fungus that grows on rye and other grains; and
- ketamine – a licensed anaesthetic.

Mescaline, 5-MeO-DMT and ibogaine have also been the subject of studies.

Medicines Framework

The majority of psychedelic compounds are still in advanced research phases, which means none of them yet has a "marketing authorisation" – a product licence issued by the Medicines and Healthcare Products Regulatory Agency (MHRA) allowing doctors to prescribe medicines for the indications for which they have been researched. Unlike cannabis, there have not yet been any exceptions made in UK law that permit psychedelic medicines to be prescribed in compassionate or special (or "unlicensed") circumstances. As such, psychedelic medicines are only available for lawful administration through clinical trials at present. Therefore, the law that applies to this area of industry at the time of writing is the MHRA framework that governs investigational medicinal products for use in clinical trials, in addition to the Home Office regime that governs controlled drugs.

Looking to the future, it may be that – as an intermediary step ahead of any licensed psychedelic medicines – there is a rescheduling such as that seen with medical cannabis in England and Wales or with psilocybin and MDMA in Australia. This would mean the legal framework that applies would be the MHRA's unlicensed medicines framework, relying on the discretion

of specialist doctors to prescribe to meet unmet clinical need, and special licensing and oversight measures within the supply chain.

In terms of the laws that govern the area, for completeness it is therefore important to mention the end-goal state – that of psychedelics as licensed medicines in the UK. Many stakeholders intend psychedelics to be subject to the same laws that govern regular medicines. There may be special stipulations attached to the marketing authorisations – for example, that they must be administered in appropriate settings and supervised by psychotherapy or psychiatry clinicians – but the hope is that recognition as treatments with a similar risk/benefit ratio to conventional treatments will facilitate access to those with the most intractable conditions.

Ketamine is a useful illustrative example of the legal framework application to psychedelic medicine. Ketamine is a controlled drug of class B and – when prescribed medicinally in pharmaceutical form – schedule II. It has a marketing authorisation so it is classed as a licensed medicine in the UK; however, it is licensed for use as an anaesthetic and not for the psychedelic properties that have been shown to relieve symptoms of depression. Therefore, ketamine as a psychedelic treatment is prescribed on an "off label"-only basis in England and Wales as a last-resort option.

Controlled Drugs Licensing and Criminal Law Frameworks

The controlled drugs framework is relevant to the practice area, primarily for researchers and drug developers at the outset of the drug development process when new compounds are explored and traditional compounds are further investigated. The framework primarily comprises the Misuse of Drugs Act (MDA) 1971, the Misuse of Drugs Regulations (MDR) 2001 and – to a lesser extent – the Psychoactive Substances Act (PSA) 2016.

The MDA 1971 is the primary piece of legislation criminalising activities involving psychedelic substances without lawful authority and captures substances under its application by expressly listing them by name (or broad chemical description). Such compounds are organised into "classes" that essentially relate to the severity of penalties for unlawful use. The MDR 2001, by contrast, establishes the framework for lawful use. Psychedelics thought to have no medicinal value in the late 1960s when the MDA 1971 was drafted sit in the most restrictive schedule known as "Schedule I".

The PSA 2016 is a piece of legislation designed to curb the rapid rise in novel psychedelic and other substances with the introduction of a blanket ban on sales of any substances that are not expressly listed in the MDA 1971 but have a psychoactive effect. It contains exemptions for researchers undertaking work under an ethics approval and other sanctioned scenarios.

The Proceeds of Crime Act (POCA) 2002 is relevant to UK entities considering investments in psychedelic medicine ventures abroad, particularly in jurisdictions with more permissive regulations than those in England and Wales. Under POCA 2002, "criminal conduct" encompasses activities that would constitute an offence if committed in the UK, regardless of their legality elsewhere. This principle is crucial for UK companies investing in international psychedelic wellness retreats, clinics and related enterprises, as revenues generated from such activity could be classified as "criminal property" under POCA 2002 – thereby potentially exposing individuals and companies to money laundering offences.

Charities Law

Owing to the benevolent nature of the industry, as well as the long-term difficulties around accessing these medicines, many charities operate in the sector. It is important for prospective charities to consider rules around providing public benefit, safeguarding and monitoring of beneficiaries, vetting of internal and external partners with regard to a broad range of risks, and rules prohibiting the promotion of treatments that are not yet licensed.

1.2 Regulatory Bodies

Medicines and Healthcare Products Regulatory Agency

The MHRA is responsible for regulating medicines, medical devices and clinical trials in the UK. The regulator approves clinical trials of psychedelic medicines to ensure safety, efficacy, and ethical compliance. The MHRA also approves the marketing authorisations for medicines once they have demonstrated quality, safety and efficacy in clinical trials and it licenses and oversees the manufacturing and distribution of medicines. The regulator also monitors adverse events and enforces pharmacovigilance requirements.

Home Office

As set out in **1.1 Primary Laws and Regulations**, the Home Office oversees the control and licensing of substances under the MDA 1971 and the MDR 2001. It issues licences for research, possession, production and supply of controlled drugs – including psychedelics classified under Schedule I (eg, psilocybin, LSD and DMT) – by exercising the powers conferred on the Secretary of State in the MDA 1971.

Care Quality Commission

The Care Quality Commission (CQC) regulates health and social care providers, including private clinics offering ketamine-assisted treatments. As the field of psychedelic medicine evolves, future private clinics offering therapies involving substances such as psilocybin (if legalised for therapeutic use) would also likely fall under the CQC's regulatory remit. This oversight ensures that such clinics comply with safety, quality and ethical standards.

Charities Commission

The Charities Commission regulates charitable organisations in England and Wales. It authorises and oversees charities supporting psychedelic research or patient access to psychedelic treatments, ensuring they operate lawfully, transparently, and in line with their stated objectives.

National Institute for Health Research and Ethical Approval Bodies

Although not a regulatory body, the National Institute for Health Research (NIHR) is pivotal in supporting research infrastructure and funding. It provides funding and guidance for research and facilitates the development of networks and collaborations between researchers, healthcare providers, and industry.

Ethical review is also a critical component of research involving psychedelic medicines. Research Ethics Committees (RECs) operate under frameworks established by the Health Research Authority (HRA) and assess clinical trial protocols to ensure the protection of participants' rights, safety, and well-being. RECs approve studies involving psychedelics, focusing on informed consent, risk mitigation, and scientific validity.

National Crime Agency

The National Crime Agency (NCA) was set up to tackle organised crime. However, it is relevant to the psychedelics industry, as it is the agency responsible for enforcing POCA 2002 and

investigating cases where UK entities profit from activities abroad that would be illegal domestically.

1.3 Self-Regulatory Authorities

At present there are no self-regulatory industry bodies.

1.4 Existing Market

The legal market for psychedelic medicine in England and Wales is restricted to ketamine prescribed off-label, predominantly privately. There is limited access to ketamine through the National Health Service (NHS) – some of which is self-pay.

The private ketamine market consists of a small number of clinics, primarily in London, where ketamine is prescribed off-label for conditions such as treatment-resistant depression and anxiety. The exact size of the market is unknown. The flagship UK ketamine clinic, Awakn, opened in 2020 and closed in 2024, citing a lack of demand for its courses of treatment – some of which cost GBP6,000. Other clinics (and self-pay NHS clinics where the drug is a generic) price single infusions in the low hundreds of pounds; however, given that multiple infusions are often part of a course of treatment, the cost can still be considerable. It is unclear how the market will continue to develop at this stage.

There is also an illicit market for psychedelic medicines, with those seeking to benefit from medicines such as psilocybin seeking out underground practitioners who offer a range of supported experiences with various psychedelic compounds. There is no reliable data on the number of people seeking healing outside the traditional healthcare system in England and Wales via the use of psychedelic compounds, but the practice appears to be growing in popularity and signals the demand for such alternative therapies.

1.5 Challenges Facing Market Participants

The psychedelic medicine market currently consists of companies devoted to bringing (often novel, patentable) psychedelic compounds to market as medicines, rather than those primarily engaged in distribution and supply through clinics and other settings. This is because, at the present moment, there is no legal route to providing the classic psychedelic compounds as medicines – with the exception of ketamine.

Although the UK has been a hub for psychedelic scientific research, and a number of prominent psychedelic companies are connected with or based in the UK, the short- to medium-term outlook for psychedelic medicine in the UK is mixed. The UK has not shown the regulatory enthusiasm for reform shown by countries such as Australia and the USA, has only granted limited government funding for research, and risks falling behind in the journey of bringing psychedelic medicines to market.

The UK is a somewhat unpredictable market for any future licensed medicine, as the main point of access to patients is the NHS and there is no guarantee that any given treatment will be included in the clinical guidelines or care pathways for a particular condition. So far, the successful licensed ketamine medicine Spravato has been rejected a number of times for recommendation by the National Institute for Health and Care Excellence (NICE), which is the gateway for general prescription on the NHS (see **3.1 Access to Psychedelic Medicines Today**).

Patent challenges are a key legal risk area, where psychedelic compounds – particularly naturally

occurring ones – may face difficulties in meeting UK patent criteria (eg, around novelty and inventive step). UK-specific patents or global IP protections may also give rise to freedom to operate (FTO) issues that restrict the commercialisation of certain treatments without appropriate licensing. Other legal risks include technical money laundering offence issues (as mentioned in **1.1 Primary Laws and Regulations** and **2.1 Common Cross-Jurisdictional Issues**) and – in rarer cases – a range of patient-orientated legal risks, such as clinical negligence, professional misconduct, and issues around informed consent to treatment.

2. Cross-Jurisdictional Matters

2.1 Common Cross-Jurisdictional Issues

Despite the difficult legal climate for the development of psychedelic medicines commercially in England and Wales, there is a relatively active community of individuals wishing to develop or invest in psychedelic businesses – often in other jurisdictions where circumstances are more favourable. Unfortunately, this is hampered by POCA 2002. As AML legislation, POCA 2002 makes it an offence in England and Wales to deal in the proceeds of crime; however, in this case, the proceeds of crime include the proceeds of activities carried out abroad that would constitute a crime if they were carried out in England and Wales. This means that investing in, for example, a Jamaican psilocybin retreat would put an investor at risk of being in breach of POCA 2002. Even though there is a defence where the conduct was not criminal conduct under the law of the relevant other jurisdiction, this does not apply where the conduct would constitute an offence punishable by more than 12 months' imprisonment in England and Wales, which is almost invariably the case with conduct involving dealing with controlled drugs.

Mitigating or avoiding the consequences of POCA 2002 is complicated for UK nationals. This has created significant issues for investors and businesspeople in the UK who wish to be involved in projects involving psychedelic medicines in other jurisdictions.

The import or export of active psychedelic substances, or precursors to them, is tightly controlled under UK and international law and is actually prohibited in many contexts. Companies must navigate Home Office and MHRA requirements domestically, as well as foreign laws that present a high degree of jurisdictional variability. Operating in multiple countries while headquartered in the UK creates complex compliance challenges due to the differing legal frameworks.

2.2 How Access Is Affected by Foreign Law and Regulation

Access to psychedelic medicines in England and Wales, unsurprisingly, is generically affected by the "mood music" from other influential global jurisdictions – although the general liberalisation of the rules in, for example, Australia and the USA does not currently seem to have any observable knock-on effect.

There are also specific provisions of the medicines licensing framework in England and Wales that mean that developments in other countries will have a direct impact on availability. The MHRA's International Recognition Procedure (IRP) was introduced in 2024 as part of the UK's regulatory framework following Brexit, replacing the EC Decision Reliance Procedure. It allows the MHRA to rely on decisions made by trusted regulatory authorities in other countries in order

to expedite the approval process for medicines and medical devices in the UK.

The relevant reference regulators are as follows:

- Australia – Therapeutic Goods Administration (TGA);
- Canada – Health Canada;
- Switzerland – SwissMedic;
- Singapore – Health Science Authority Singapore (HSA);
- Japan – Pharmaceuticals and Medical Devices Agency (PMDA)
- USA – the US Food and Drug Administration (FDA)
- EU/European Economic Area (EEA) – European Medicines Agency (EMA) and the competent authorities of EU member states, Norway, Iceland and Liechtenstein.

The expedited approval process can be significantly faster than the standard review process. The MHRA can rely on the assessment reports from the recognised regulatory authorities, thereby reducing duplication of effort as well as speeding up the review process. However, the MHRA still maintains the right to request additional information or conduct its own assessment if deemed necessary.

For patients to benefit from the IRP, psychedelic medicines must be licensed in those other jurisdictions and subsequently an application needs to be made in the UK by the medicine's developer. There was some excitement around the potential of the Lykos Therapeutics application for a marketing authorisation for midomafetamine (MDMA) in the USA for exactly that reason. However, even if the application had succeeded, there is no strong indication that Lykos Therapeutics would have attempted to use the US marketing authorisation to apply for an authorisation in the UK using the IRP. The IRP has significant potential to expedite access to psychedelic medicines for the UK public, but so far that potential has been unexplored.

3. Legal and Regulatory Developments

3.1 Access to Psychedelic Medicines Today

Access to medical psychedelics is limited by the fact that no psychedelic is a licensed medicine in England and Wales. Given that they are Schedule I substances (apart from ketamine, if this is being included within the definition of "psychedelic"), they cannot be prescribed as "unlicensed" medicines by doctors.

The lack of licensed medicines is down to the same factors as other jurisdictions – ie, full clinical trials have largely yet to be completed. However, in England and Wales, it is also possible for doctors to prescribe "unlicensed" medicines – this is how the private medicinal cannabis market in England and Wales has been able to develop. In order for cannabis to become a medicine it first had to be taken out of Schedule I of the MDR 2001, which happened (partially) in 2018. If the compounds used in psychedelic medicine were removed from Schedule I, then a similar situation could arise with doctors prescribing them as "unlicensed" medicines – although, given the general requirement for supervision of patients using psychedelic medicine, this would be a far more complicated proposition than the current unlicensed cannabis medicine ecosystem.

The Home Office has received calls to look into the rescheduling of psilocybin into Schedule II under the MDR 2001. However, so far, the UK government's line has been that there are path-

ways in place to develop medicines containing Schedule 1 substances and that rescheduling is therefore unnecessary.

Even once licensed psychedelic medicines are available in England and Wales, this will not necessarily guarantee widespread access to them. This is because the vast majority of people in England and Wales receive medical treatment through the NHS and, in order to be prescribed by NHS doctors, a medicine must generally first be assessed and then recommended by NICE. The experience of Spravato with NICE is informative – despite being available in 20 other countries across Europe (including Ireland and Scotland), it has been assessed by NICE multiple times and not recommended for NHS funding. Given the complex and likely expensive delivery mechanisms for future psychedelic medicines, there is every chance that they will encounter the same difficulties.

3.2 Legislative Routes to Wider Access

There are two primary likely routes to market access in England and Wales, as follows.

- A psychedelic medicine completes clinical trials and becomes available as a licensed medicine on the NHS and/or privately.
- Psychedelic compounds are rescheduled and an ecosystem for prescribing them as "unlicensed" medicines – along with an infrastructure for patients to safely use them – emerges, as has been the case with cannabis.

3.3 Adult-Use Markets

It is unclear how close England and Wales is to an adult-use market. This is because the approach of the new Labour government to the topic of drug reform in its recent election campaign was to not mention it at all, either positively or negatively. This was part of a strategy of avoiding saying anything that might put off swing voters or traditional Conservative party voters who might be discouraged from voting Labour if they made positive noises about drug reform. However, it means that there is little to go on when trying to predict whether Labour – a left-of-centre party – will be open to following the increasing number of jurisdictions that have begun to explore loosening controls around psychedelics.

Simply from the perspective of progressing from less controversial to more controversial substances, it seems highly unlikely that there will significant deregulation around psychedelics prior to this happening with cannabis. Hence, for those monitoring England and Wales, then progress in the creation of an adult-use market for cannabis will be the first indicator to look for.

USA

Law and Practice

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1. Regulatory Overview

1.1 Primary Laws and Regulations

The Controlled Substances Act

In the United States, psychedelic substances are regulated through both federal and state laws. On the federal side, the main governing statute is the Controlled Substances Act (CSA) of the Comprehensive Drug Abuse Prevention and Control Act of 1970. See Gonzales v Oregon, 546 U.S. 243 (2006). The CSA establishes a comprehensive federal scheme to regulate the manufacturing and distribution of controlled substances. To that end, the US Congress recognised that drugs "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people", 21 U.S.C. § 801(1), but that the "illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people". Id. § 801(2). The CSA classifies controlled substances into five schedules.

- Schedule I contains substances with the highest risk, deemed to have no accepted medical use, and a high potential for abuse.
- Schedule II contains substances with a similarly high risk, an accepted medical use, and a high potential for abuse.
- Schedule III contains substances with moderate risk, an accepted medical use, and a moderate potential for abuse.
- Schedule IV contains substances with lower risk, an accepted medical use, and a low potential for abuse.
- Schedule V contains substances with the lowest risk, an accepted medical use, and the lowest potential for abuse.

The CSA prohibits manufacturing, possessing, using, and distributing any substances that are classified under Schedule I, absent a DEA registration. The classic psychedelics, which include psilocybin, dimethyltryptamine (DMT), mescaline, methylenedioxymethamphetamine (MDMA), lysergic acid diethylamide (LSD), and ayahuasca, are all classified under Schedule I. Other substances that are not classified as psychedelics but that have psychedelic effects at higher doses, such as ketamine, are classified differently. Ketamine is classified as Schedule III.

Generally, substances in more restrictive schedules are criminalised more strictly, with Schedule I substances such as psychedelics subject to the most severe penalties. See 21 U.S.C. § 841. The CSA singles out LSD for particularly harsh penalties: distributing "1 gram or more of a mixture or substance containing a detectable amount of [LSD]" bears the same penalty as distributing over 500 grams of cocaine or 100 grams of heroin. Id. § 841(b)(1)(B)(v). The US Supreme Court has noted that "there may be little in logic to defend the statute's treatment of LSD; it results in significant disparity of punishment meted out to LSD offenders relative to other narcotics traffickers". Neal v United States, 516 US 284, 295 (1996).

The Federal Food, Drug and Cosmetic Act and "Right to Try" Laws

Controlled substances in Schedule I have been deemed to have no "medical use in treatment in the United States" and a high abuse potential. Notwithstanding that designation, multiple psychedelics have proven safe. Both psilocybin and MDMA have been in stage III clinical trials at the US Food and Drug Administration (FDA) and have achieved the designation of "breakthrough therapy". See the discussion below on FDA's breakthrough therapy designation.

The federal statute governing clinical trials is the Food, Drug, and Cosmetic Act (FDCA). 21 U.S.C. §§ 301–392. The stated purpose of the FDCA is to protect consumers from various risks associated with drugs and biological products. FDA enforces the provisions of the FDCA through administrative proceedings, enforcement actions, and civil and criminal penalties. In general, before a new drug can be introduced into the market, FDA must approve its new drug application or biologics licence application, which must include data from clinical trials. To get this process started, the sponsor of a clinical trial must submit an investigational new drug (IND) application, requiring submission of specific information and compliance with a long list of requirements, to FDA for permission to test the drugs on human subjects. If the application is approved, then the sponsor generally must embark on three phases of clinical trials. An individual may be able to access an IND through a clinical trial.

Investigational new drug laws under the FDCA

While psychedelics are controlled substances, federal law regulating their therapeutic use and study has shifted over the years. In 1987, Congress, FDA, and the medical community at large redefined when certain unapproved developmental medicines could and should be used with seriously ill patients.

In May 1987, FDA released final rules (the "IND Rules") outlining formal procedures "under which promising investigational new drugs may be made available to desperately ill patients before general marketing begins". 52 Fed. Reg. 19466-01. These rules, which were the first formal implementation of several initiatives to ease and expand access to certain drugs for the treatment of serious and life-threatening conditions, tracked FDA's 1982 interpretation of "statutory language of 'accepted medical use with severe restrictions'". See 47 Fed. Reg. 28141-01 (29 June 1982) (quoting 21 U.S.C. § 812(b)(2)(B)); 12 FDA Drug Bull. 4, 5 (April 1982). According to FDA, its rules were "intended to facilitate the availability of promising new drugs to patients as early in the drug development process as possible, and to obtain additional data on the drug's safety and effectiveness". IND Rules, 52 Fed. Reg. 19466-01.

Since 1987, FDA has refined its IND regulations "to improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions who lack other therapeutic options and who may benefit from such therapies" and to "facilitate wider availability of investigational drugs in appropriate circumstances". 74 Fed. Reg. 40900-01, at 40902 (13 August 2009). While the resulting IND Rules had established regulations for using investigational drugs, they did not establish eligibility criteria for such uses, leading to inconsistent policies and access. Id.

To remedy this issue, Congress amended the FDCA in 1997 to facilitate expanded access (otherwise known as compassionate use). Id. at 40900 (citing 21 U.S.C. § 360bbb). In 2009, the Expanded Access Rule implemented the amended FDCA and amended FDA regulations to make investigational treatments available to patients before FDA approval in three situations: (i) to individuals in emergencies; (ii) to intermediate-size patient populations; and (iii) under an expanded-access treatment protocol. 74 Fed. Reg. 40900-01, 40901 (13 August 2009). According to FDA, these enumerated categories reflect consensus in the medical community and balance competing concerns surrounding expanded access. Id. The regulations give

"patients a meaningful and reasonable measure of autonomy over their own healthcare decisions while preserving the integrity of the drug approval process and protecting patient safety". Id. at 40902. FDA gradually moved away from a hardline stance on developmental drugs and new uses of drugs in favour of the greater flexibility asked for by the medical community and patients. However, in practice, access to psychedelics, as developmental drugs, has been hampered by their Schedule I designation, see infra **1.1 Primary Laws and Regulations** and the discussions on Federal and state right-to-try laws and Recent developments in federal case law.

FDA's breakthrough therapy designation

Shortly after promulgation of the 1987 IND Rules, FDA established a second pillar to expedite the development of life-saving treatments. See 53 Fed. Reg. 41516-01, 41519 (21 October 1988) (codified at 21 C.F.R. §§ 312.80–.88, 314.125). This rule aimed "to speed the availability of new therapies to desperately ill patients, while preserving appropriate guarantees of safety and effectiveness" and "to facilitate the development, evaluation, and marketing of such products, especially where no satisfactory alternative therapies exist". Id. at 41516. The rules "reflect the recognition that physicians and patients are generally willing to accept greater risks or side effects from products that treat life-threatening and severely debilitating illnesses, than they would accept from products that treat less serious illnesses". 21 C.F.R. § 312.80.

In 2012, Congress expanded the expedited-review protocol. Recognising that "[p]atients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases or conditions", Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112–144, 9 July 2012, 126 Stat. 1083, Congress statutorily defined a "breakthrough therapy" as a drug intended to treat "a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies". 126 Stat. at 1086 (codified at 21 U.S.C. § 356(a)).

FDA expounded on this definition in a 2014 Guidance, entitled Guidance for Industry, Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014). There, it explained that for a drug to achieve a breakthrough therapy designation, FDA must identify preliminary evidence sufficient to indicate that the drug may show substantial improvement in effectiveness or safety over available therapies, but in most cases not sufficient to establish safety and effectiveness for approval. 2014 Guidance at 11.

In 2017, FDA designated two psychedelics, psilocybin and MDMA – and in 2024, LSD as well – as breakthrough therapies, expediting the study of psilocybin for depression, MDMA for post-traumatic stress disorder, and LSD for generalised anxiety disorder in clinical trials.

Federal and state right-to-try laws

Between 2014 and 2018, as FDA overhauled its expanded access regulations, 41 states enacted Right-to-Try (RTT) laws, allowing psychedelics to be used in limited situations for medical applications involving terminally ill patients.

In 2018, Congress followed suit by adding § 561B to the FDCA, "establish[ing] national standards and rules by which investigational drugs may be provided to terminally ill patients" and providing an exemption to the statute's safety/efficacy requirement, permitting therapeutic use of "unapproved" drugs by terminally ill patients

under specified conditions and allowing use of unapproved investigational drugs that have successfully completed Phase 1 clinical trials with dying patients.

These RTT laws underscore the paradigm shift that FDA and Congress have recognised since the late 1980s: in certain circumstances, investigational or developmental drugs should be available (with severe restrictions) for patients with life-threatening illness.

Even so, the US Drug Enforcement Administration (DEA) has steadfastly refused all requests to access psychedelics under RTT laws. A bill introduced in 2022, S.B. 4575, would have amended the federal RTT statute to expressly include Schedule I substances, but the bill died in committee.

Recent developments in federal case law

The disconnect between the passage of RTT laws and their application has prompted the need for litigation. A salient example is Advanced Integrative Medical Science Institute PLLC v Garland, 24 F.4th 1249 (9th Cir. 2022). In early 2021, Petitioner Dr Sunil Aggarwal sought to provide psilocybin to his terminally ill patients for therapeutic use under Washington state's RTT law. Yet, because of psilocybin's Schedule I status, no supplier would provide Dr Aggarwal with psilocybin without DEA consent. Despite Dr Aggarwal's multiple proposals to DEA to legally permit him limited access to psilocybin for use under state and federal RTT, DEA rejected each request, claiming that the CSA trumps the RTT. Left with no choice, Dr Aggarwal petitioned the US Court of Appeals for the 9th Circuit to review DEA's decision. Following oral argument, the case remains pending in the 9th Circuit.

In a related case, in which Dr Aggarwal sought judicial relief related to DEA's denial of his petition to reschedule psilocybin, the 9th Circuit granted his petition and remanded to DEA to reconsider rescheduling psilocybin. See Aggarwal v US DEA, No 22-1718, 2023 WL 7101927, at *2 (9th Cir. 27 October 2023).

Attorneys from the law firms Perkins Coie, LLP, Porter Wright Morris & Arthur LLP, and Yetter Coleman LLP, as well as the National Psychedelics Association, represent AIMS and Dr Aggarwal in these actions.

State Law

While psychedelics remain illegal federally, the story is different in some states. Most notably, Oregon and Colorado have legalised psilocybin for psychedelic-assisted therapy.

- Oregon – in November 2020, Oregon became the first US state to legalise psychedelic-assisted therapy with the passage of Ballot Measure 109, creating an assisted therapy programme for administering psilocybin products to individuals aged 21 and older. Oregon voters also approved Ballot Measure 110, which decriminalised possession of small amounts of all substances, including psychedelics. In 2024, drug possession was recriminalised through House Bill 4002, but the licensed sale and therapeutic use of psilocybin remains legal under Measure 109.
- Colorado – in November 2022, Coloradans voted to pass Proposition 122, which legalised consumption of psilocybin in a service centre with a state-licensed professional. Proposition 122 also decriminalised personal possession, growth, sharing, and use of natural psychedelic substances for individuals aged 21 and over. Colorado's legalised

service centres are expected to become operational in early 2025.

The following states have either passed bills or are considering legislation legalising some therapeutic use of psychedelics.

- Utah – in March 2024, Utah governor Spencer Cox signed into law Senate Bill 266, creating a pilot programme that allows doctors at the University of Utah Health and Intermountain Health the option to treat patients with psilocybin and MDMA. The law went into effect on 1 May 2024, but no patients have been treated because of an inability to access psilocybin. Utah also created a task force to provide recommendations on any "psychotherapy" drug when treating mental illness, but that work is on hold pending federal permissibility.
- Massachusetts – Massachusetts Question 4, titled "Legalization and Regulation of Psychedelic Substances Initiative", was on the 5 November 2024 ballot. If it had been passed, it would have legalised growth, possession, and use of a personal amount of psychedelics and legalised their supervised administration at licensed treatment centres. It was, however, rejected.
- New Jersey – in October 2024, Bill A3862 advanced to the full New Jersey Senate for consideration. If passed, New Jersey would become the third state to legalise supervised psilocybin services, allowing for the therapeutic/clinical use of psilocybin in regulated settings. The bill creates a 15-member advisory board to roll out the programme and a licensing process over an 18-month period.
- Arizona – in June 2024, Arizona governor Katie, Hobbs signed Senate Bill 1677, which permits providing workers' compensation for MDMA-assisted therapy for treatment of post-traumatic stress disorder (PTSD) among firefighters/certified peace officers, should MDMA be federally legalised.
- Nevada – in January 2024, Nevada passed Senate Bill 242, establishing a working group to study issues relating to therapeutic use of entheogens.
- Texas – in June 2021, the Texas legislature enacted House Bill 1802, allowing research at the Baylor College of Medicine and the Michael E. DeBakey VA Medical Center to conduct studies on alternative therapies, including the use of MDMA, psilocybin and ketamine, in treating PTSD.

Other US states are considering bills regarding psychedelic substances or have had cities move to decriminalise psychedelic substances.

- California – while psychedelic substances are not yet legal at the state level, Oakland, Santa Cruz, Arcata and San Francisco have decriminalised entheogens such as psilocybin, by deprioritising enforcement on these psychedelic substances.
- Connecticut – the Connecticut House of Representatives is considering House Bill 5297, concerning decriminalisation of possession of small amounts of psilocybin. Senate Bill 1063 includes provisions for establishing a working group to study psilocybin's health benefits.
- Hawaii – the Hawaii House of Representatives is considering House Bill 1340, which would establish a Temporary Breakthrough Therapy Designation Advisory Council within three months of certain breakthrough therapy designation approvals by FDA.
- Maryland – Maryland lawmakers are considering several bills that would implement actions related to psychedelic substances, including establishing task forces for making recommendations on psychedelic policies

and establishing funding for studying alternative therapies to PTSD treatment. See HB 548, 709, 1009.
- Vermont – the Vermont Senate is considering Senate Bill 114, which would establish a working group to make recommendations on whether to establish a programme similar to programmes in Colorado or Oregon.
- Washington – the Washington Senate is considering Senate Bills 5263 and 5693 to assess the feasibility of enacting a measure similar to Oregon's Measure 109.

In addition, at the time of this writing, Illinois, Indiana, Maine, Missouri, New York, Oklahoma, Rhode Island, Virginia, and West Virginia are also considering bills related to psychedelic substances, including potentially legalising the therapeutic use of such substances.

1.2 Regulatory Bodies

The US Drug Enforcement Administration (DEA)

Scope of authority

At the federal level, the regulatory body that implements and enforces the CSA is DEA. DEA designates substances (which include psychedelic substances) for control. That includes substances controlled through formal rulemaking if the substance satisfies the applicable statutory criteria and FDA scrutiny. See 21 U.S.C. § 811(a) and (b). DEA may also designate a substance for control if required by the international treaty obligations of the United States. DEA's mandate includes two sets of provisions of the CSA.

- Trafficking provisions – establish penalties for the production, distribution, and possession of controlled substances outside the legitimate scope of the registration system. See 21 U.S.C. §§ 841-865, 871-890.
- Registration provisions – require individuals and entities working with controlled substances to register with the federal government, take steps to prevent diversion and misuse of controlled substances, and report certain information to regulators. See 21 U.S.C. §§ 821-832.

Violations of the registration provisions of the CSA generally do not rise to the level of criminal offences, but DEA may refer serious violations for criminal prosecution, which may yield fines and even prison sentences. Violations of the CSA's trafficking provisions are criminal offences, carrying large fines and lengthy prison sentences.

DEA's scheduling authority and FDA's scope of authority

In addition to enforcement, DEA implements the CSA by making scheduling decisions through an interagency administrative process. DEA may undertake administrative scheduling on its own initiative, at the request of the US Department of Health and Human Services (HHS), or on an interested party's petition. If DEA denies a petition to begin scheduling proceedings, that denial is subject to judicial review, where the standard for overturning a denial is the "arbitrary and capricious" standard. Ams. for Safe Access v DEA, 706 F.3d 438, 440 (D.C. Cir. 2013).

Before initiating rulemaking proceedings, DEA must request a scientific and medical evaluation of the substance from HHS, which has delegated this role to FDA. FDA considers many factors in the scientific and medical evaluation, including the substance's potential for abuse and dependence, scientific evidence of its pharmacological effect, the state of current scientific knowledge regarding the substance, any risk the substance poses to the public health, and whether the substance is an immediate precursor of an exist-

ing controlled substance. After evaluating these factors, FDA makes a recommendation to DEA on whether the substance should be controlled and, if yes, where it should be placed on the schedule. DEA is required to defer to FDA and HHS on matters involving scientific and medical use. See Gonzales, 546 US at 265. DEA must defer to FDA's medical and scientific conclusions, but DEA may place drugs on a different schedule than that recommended by FDA. See Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C. _, slip op. at 4 (11 April 2024).

Legalised States' Regulatory Bodies

In states that have legalised psychedelic substances (at the time of this writing, Oregon and Colorado), usage of certain psychedelic substances by people over age 21 is legal under the supervision of licensed providers. In those states, the scope of authority for regulatory bodies focuses on licensure and regulating the manufacturing, transportation, delivery, sale, and/or purchase of the legalised psychedelic medicine. These regulatory bodies include Oregon Psilocybin Services, within the Oregon Health Authority Public Health Division's Center for Health Protection, and the Colorado Department of Regulatory Agencies and Department of Revenue.

1.3 Self-Regulatory Authorities

Self-regulating authorities are essentially non-existent in psychedelics.

1.4 Existing Market

There is no legal commercial marketplace in psychedelics. The regulated psychedelic-assisted therapy market in Oregon is estimated to be valued between USD2.8–8.8 million (Colorado will not start opening legal treatment centres until 2025). Companies engaged in clinical trials of psychedelics have a combined valuation of around USD600 million, though it is difficult to estimate true market size due to the lack of organised markets for psychedelics. There are no recent, reliable estimates for the scope of the illicit market.

1.5 Challenges Facing Market Participants

Tensions Between Federal and State Law

There are tensions between federal and state law that currently make it difficult to effectuate real progress. While states move to decriminalise, legalise, or regulate psychedelics, the federal government still treats psychedelic substances as controlled substances with no medical utility and an abuse potential higher than cocaine and fentanyl. This challenge applies to all market participants involved in the possession, sale, or use of psychedelic substances, including federally unregistered research into these substances.

Currently, it appears that DEA and FDA are, for the most part, taking a hands-off approach. But that does not mean that priorities and policies could not change at any moment, particularly with a change in administration. In short, despite Oregon and Colorado legalising the use of psychedelic substances for assisted therapy (and other states considering it), these medicines remain illegal at the federal level and in the vast majority of states, even if federal and state agencies have deprioritised enforcement.

Licensure Issues Under State Law

Market participants in Oregon and Colorado also face risks associated with licensing laws regarding the sale and use of psychedelic substances. Should market participants not be properly licensed for legal sale and use of psychedelic substances, they may face state penalties if they do not follow procedures to obtain state licences

as well as the looming threat of federal enforcement.

Liquidation and Bankruptcy

The tensions between federal and state law also extend to liquidation and/or bankruptcy procedures that market participants may face. Because psychedelic substances are federally regulated as Schedule I substances, market participants do not have access to federal bankruptcy proceedings and procedures. As such, market participants winding down their businesses may face the risk of having to liquidate and/or distribute assets without the benefit and protection of federal bankruptcy proceedings. This presents a unique legal risk for market participants, particularly in the context of the inherent market volatilities.

2. Cross-Jurisdictional Matters

2.1 Common Cross-Jurisdictional Issues

Federal Pre-emption – Cannabis Analogue

In the past two decades, 38 states have enacted medical-use cannabis programmes and 24 have enacted recreational programmes, despite cannabis being classified as Schedule I under federal law. This friction between state legalisation and federal pre-emption by the CSA has been resolved, for the most part, by deliberate federal non-intervention. In 2013, the US Department of Justice (DOJ) released what is now known as the "Cole Memo". The Cole Memo stated that state medical-use cannabis programmes could minimise the risk of federal intervention by self-regulating in accordance with DOJ's interests in enforcing the CSA.

- Preventing the distribution of marijuana to minors.
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels.
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states.
- Preventing state-authorised marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity.
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana.
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use.
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands.
- Preventing marijuana possession or use on federal property.

Many states appropriated this guidance to create their medical and adult-use cannabis programmes and have since regulated with minimal federal intervention.

Psychedelics face similar challenges, and the Cole Memo is instructive to practitioners and state governments navigating the legalisation of psychedelic substances. Like cannabis, psychedelic substances are classified as Schedule I. The lessons of state cannabis legalisation and the lack of federal enforcement of the CSA may provide guidance for states and serve as useful models for other experimental medical-use and/or therapeutic use programmes for Schedule I drugs. See also **3.3 Adult-Use Markets**.

Still, DOJ's public stance on the CSA can and has changed with new administrations. For example, in 2018, DOJ under the Trump administration

rescinded the Cole Memo's non-interventionist enforcement of the CSA. However, in the years since, the federal regulatory landscape has remained substantially unchanged. Thus, although the Cole Memo was published more than a decade ago, it nonetheless remains a helpful analogue for minimising potential federal intervention in medical-use psychedelics programmes. To date, there has been no explicit federal guidance on state psychedelics laws, despite two states legalising psychedelic-assisted therapy.

State Legalisation and Local Bans

Even after a state legalises psychedelics, the municipalities and cities within that state may have the ability to ban those substances. Oregon and Colorado have taken different approaches to such local bans. In Oregon, Measure 109, which legalises psilocybin use, allows for cities and municipalities to maintain a ban on psilocybin. Presently, 25 counties and over 100 cities in Oregon maintain a ban and opt out of the state legalisation programme.

On the other hand, Colorado's Proposition 122 prohibits municipalities and cities from banning access to psychedelic-assisted therapy. In practice, it is important to understand local laws or regulations on psychedelic substances (if any) before taking any action.

Dormant Commerce Clause

The Cole Memo highlights that one of DOJ's chief concerns about Schedule I substances is interstate diversion. Many states have self-regulated around this issue in cannabis legislation by prohibiting the transportation or sale of cannabis outside the state.

The dormant commerce clause (DCC) limits states' ability to regulate commerce in their state with regulations that are facially discriminatory against citizens of other states or with regulations that unduly burden interstate commerce. The DCC generally does not allow states to restrict commercial rights afforded by that state to the residents of other states absent congressional approval or a showing of a compelling state interest. For example, durational residency requirements for obtaining a commercial licence, such as a liquor licence, are usually subject to strict scrutiny. See – eg, Tenn. Wine & Spirits Retailers Ass'n v Thomas, 588 US 504, 513-514 (2019). Likewise, a regulation that unduly burdens interstate commerce with negligible benefits to the enacting state violates the DCC, such as a requirement that all trucks driving in a state have uniform mudflaps despite many travelling interstate. See Bibb v Navajo Freight Lines, Inc., 359 US 520, 529 (1959). Federal courts, however, are split on whether to apply the DCC to protect the interstate market for Schedule I substances. See Tommy Tobin & Andrew Kline, A Sleeping Giant: How the Dormant Commerce Clause Looms Over the Cannabis Marketplace, Yale L. & Pol'y Rev., 3 January 2022.

Once again, the cannabis industry provides a useful analogue. Most courts have upheld DCC protection in the cannabis industry by striking down state residency requirements in cannabis programmes. Id. Some jurisdictions, however, such as Oklahoma, have abstained from ruling on the issue, and others, such as Washington, have upheld state residency requirements for cannabis programmes. The reason for the split is the federal illegality of cannabis, so practitioners should expect jurisdictions to have similarly conflicting positions in applying DCC protection to other Schedule I substances, including psychedelics. Practitioners should research the target state's treatment of cannabis under the DCC to inform their decision-making on psychedelic substances.

2.2 How Access Is Affected by Foreign Law and Regulation

United Nations Convention on Psychotropic Substances

The current international framework governing countries' legal regimes on psychedelic substances is formed by the United Nations (UN) Treaty on Psychotropic Substances (the "1971 Convention"), UN Single Convention on Narcotic Drugs of 1961 (the "Single Convention"), and UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. International Narcotics Control Board (INCB), Annual Report 2023: Chapter II, INCB 17 (2023).

There are currently 184 parties to the 1971 Convention, including the United States. The 1971 Convention contains a similar classification system to the CSA. Like the CSA, Schedule I classification under the 1971 Convention is the most restrictive class, and the treaty "prohibit[s] all use [of Schedule I substances] except for scientific and very limited medical purposes" in designated places either controlled by the government or with specific governmental approval. 1971 Convention, 21 February 1971, 32 U.S.T. 543, Article 7. Further, the 1971 Convention prohibits the "manufacture, trade, distribution and possession" of the substances without prior authorisation or a special licence and requires supervision and recordkeeping. Id. Imports and exports are only permitted when both parties are competent agencies or authorities or are specifically authorised by said authorities. Id. Under the 1971 Convention, DMT, LSD, mescaline, MDMA, psilocybin, and tetrahydrocannabinol (also known as THC) have been classified by the UN as Schedule I substances. See INCB, List of Psychotropic Substances Under International Control, INCB 5 (2022).

Importantly, the 1971 Convention framework is not as restrictive as the CSA. The CSA states that Schedule I substances have no currently acceptable medical use, whereas the 1971 Convention finds its designated Schedule I substances to have at least "very little medical purpose". Additionally, the 1971 Convention does not apply to the plants that contain the psychotropic substances, but the CSA does. Joanna R Lampe, The Controlled Substances Act (CSA): A Legal Overview for the 118th Congress, Cong. Research Serv. Report No R45948, at 1 n.5 (19 January 2023) ("CSA: A Legal Overview").

International Obligations and the CSA

The 1971 Convention and the Single Convention are not self-executing treaties, meaning they do not hold the force of law in the United States or other countries unless the country passes domestic laws to implement those treaties.

Domestically, the CSA contains a provision that requires the US Attorney General to issue an order remedying any non-adherence to international treaties, conventions or protocols in effect on 27 October 1970, without regard to the fact-finding and formal rulemaking requirements elsewhere in the Act. 21 U.S.C. § 811(d)(1); Joanna R Lampe, CSA: A Legal Overview at 35 n.334. The provision does not apply to substances controlled under the 1971 Convention, including most psychedelic substances. § 811(d)(1). Regardless, whether this CSA provision is enforceable is debatable: it has been posited that this portion of the CSA may be a violation of the private non-delegation doctrine. See Shane Pennington and Matt Zorn, The Controlled Substances Act: An International Private Delegation That Goes Too Far, 100 Wash. Univ. L. Rev. Online 29, 50 (2023).

The relevant CSA provisions on psychotropic substances state that upon notification of a scheduling decision under Article 2 of the 1971 Convention, or upon notice that the CSA and FDCA do not meet the requirements of controlling a psychotropic substance under the treaty, the HHS Secretary must consult with the Attorney General and determine whether existing legal controls are sufficient. 21 U.S.C. § 811(d)(2)–(4). Depending on whether the HHS Secretary believes the controls are sufficient to meet the 1971 Convention's obligations, the Secretary may initiate formal rulemaking to change the substance to a schedule with more appropriate controls. Id. And if the formal rulemaking process will not be completed in time to meet international obligations, the CSA allows temporary rescheduling of the substance to Schedule IV or V. Id. § 811(d)(4).

In effect, the United States must satisfy its treaty obligations regulating psychedelics. But the United States need not match the 1971 Convention's Schedules lockstep as evidenced by the government's guidance on the treaty implications of rescheduling cannabis. The federal guidance on cannabis found that international obligations may be met through scheduling and additional regulations, as opposed to scheduling alone. See the discussion below on the Federal Guidance on Cannabis and the Effect on Treaty Obligations. What this means for psychedelic substances is that, because they are classified as Schedule I under the 1971 Convention, any US rulemaking process to reschedule psychedelic substances must be balanced with the international treaty obligations of the United States.

Federal Guidance on Cannabis and the Effect on Treaty Obligations

The mechanics and associated treaty implications of rescheduling a Schedule I substance under the CSA are on full display with potential rulemaking procedures to reschedule cannabis to Schedule III. See Joanna R Lampe, Legal Consequences of Rescheduling Marijuana, Cong. Research Serv. Report No LSB11105 (1 May 2024); see also Joanna R Lampe, CSA: A Legal Overview at 12, 35, 37.

Although cannabis is generally governed by the Single Convention, US obligations at the international level are comparable between the Single Convention and the 1971 Convention with slight variations and applicability. If cannabis is successfully rescheduled to Schedule III under the CSA, that could provide an important roadmap for psychedelic substances' potential rescheduling. DOJ's Office of Legal Counsel (OLC) determined that both the CSA and the Single Convention allow DEA to satisfy the treaty obligations of the United States through a combination of rescheduling cannabis and implementing additional regulations. See Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C. slip op. at 28 (11 April2024). Specifically, OLC assessed that placing cannabis in a Schedule III designation under the CSA would not violate the Single Convention's obligations, so long as additional controls are introduced to close the "modest gap" between CSA's Schedule III controls and the Single Convention's Schedule I designation. Id. The federal government had previously believed that US treaty obligations would not allow gap-filling regulations when a Schedule regime itself does not fully meet international obligations. But congressional amendments to the CSA show that a substance can be scheduled lower on the CSA and still be subject to registration regulations and import/export authorisations – which meet international obligations. Id. at 31–34.

Applied to psychedelic substances, OLC's guidance makes it clear that treaty obligations can be met through a mix of scheduling and supplemental regulations. This means that, like cannabis, psychedelics could be scheduled to a lower CSA schedule, despite being Schedule I under the 1971 Convention. Moreover, the 1971 Convention also does not include regulations on plants containing psychedelic substances, making compliance slightly easier compared to cannabis.

Indigenous and Traditional Use Permitted

Finally, the 1971 Convention contains a carve-out for indigenous plants that contain psychotropic substances when they are traditionally used by "certain small, clearly determined groups in magical or religious rights". 1971 Convention, 21 February 1971, 32 U.S.T. 543, Article 32. Countries utilising this provision make reservations regarding these wild plants at the time of signing, ratification, or accession and opt out of the Schedule I designation, except for importation and exportation. Id. Because the 1971 Convention also does not apply to plants, there is more opportunity for reform in this space regarding psychedelic substances' use in magical or religious rights.

The United States has already created a carve-out for Native Americans who use peyote for traditional ceremonial uses. See 42 U.S.C. § 1996. Likewise, in Mexico the indigenous and ceremonial use of peyote and psilocybin are exempted from prosecution. Other countries have embraced psychedelic substances as part of their cultural heritage and legalised their traditional use, such as Peru declaring traditional uses of ayahuasca in native Amazon communities as "Cultural Patrimony of the Nation", and Brazil's regulatory regime allowing traditional ayahuasca use. That said, despite other countries' allowance of psychedelic medicine for ceremonial and traditional use, support in the United States for such non-medical use, beyond the specific carve-out mentioned above, is lagging. DEA is also able to grant religious exemptions when petitioned under the federal Religious Freedom Restoration Act, but the agency rarely grants exemptions to religious groups absent litigation. Iowaska Church of Healing v Werfel, 105 F.4th 402 (D.C. Cir. 2024).

3. Legal and Regulatory Developments

3.1 Access to Psychedelic Medicines Today

Present State of Psychedelic Medicine

As discussed at length in **1. Regulatory Overview**, access to medical psychedelics is currently prohibited by both federal law and most state laws in the United States.

Under the CSA, all classic psychedelics (LSD, psilocybin, mescaline, DMT, etc), as well as MDMA are placed in Schedule I. It is therefore federally illegal in the United States for physicians to prescribe classic psychedelics for any medical purpose. Given the stringent rules governing Schedule I drugs, it is also quite difficult to legally conduct medical research on these substances.

Unlike the classic psychedelics, ketamine is placed in Schedule III. Consequently, although FDA has not approved it for such purposes, physicians may prescribe ketamine off-label for mental health issues. There are currently over 500 legal ketamine therapy clinics in the United States.

Many state legislatures have contemplated legalisation of psychedelic-assisted therapy, particularly with psilocybin. Although some such

efforts are still under consideration, of those that have gone to a vote, most have failed. Oregon and Colorado are notable exceptions. By approving Ballot Measure 109 in 2020, Oregon voters legalised psilocybin-assisted therapy at licensed treatment centres in the state, openly defying federal law. In 2022, Colorado voters did the same with Proposition 122.

As of 2024, Oregon and Colorado remain the only states with access to legal psychedelic-assisted therapy. Several states are also considering similar bills and/or ballot initiatives. See **1.1 Primary Laws and Regulations**.

Future Trends

Although psychedelic medicine remains generally illegal, regulators and legislatures have shown keen interest in exploring the drugs' medical potential.

At the federal level, the 2024 National Defense Authorization Act included a bipartisan provision authorising the Department of Defense to fund research on the use of psychedelics as treatment for PTSD and other mental health issues in veterans.

FDA has granted "breakthrough therapy" status to psilocybin, LSD, and MDMA, fast-tracking the review process. Studies of the use of MDMA for PTSD, led by the Multidisciplinary Association for Psychedelic Studies (MAPS) and Lykos Therapeutics, have reached Phase 3 large-scale human trials – the final hurdle for FDA approval. But in August 2024, FDA declined Lykos's application to approve MDMA as a treatment for PTSD in psychiatric-assisted therapy, citing insufficient data of safety and efficacy. FDA requested that Lykos conduct additional research. Meanwhile, Compass Pathways is conducting Phase 3 trials of psilocybin for treatment-resistant depression, and MindMed has achieved promising results in its Phase 2 trials of LSD for generalised anxiety disorder.

If FDA were to approve one or more psychedelic substances for a medical purpose, that would contradict the "no accepted medical use" criterion for Schedule I designation. FDA approval would thus put pressure on DEA to consider rescheduling the substances. Although DEA is not obligated to reschedule substances in response to FDA approval, DEA is required to defer to FDA on the questions of medical use and safety. Gonzales, 546 US at 265; Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C. slip op. at 4. (11 April 2024). For example, in 2016 DEA declined to reschedule cannabis, taking FDA findings regarding safety and medical applications as conclusive. 81 Fed. Reg. 53688-01 (12 August 2016).

On the state level, many state legislatures have created task forces, advisory groups, or pilot research programmes to study psychedelics and recommend policy changes. See **1. Regulatory Overview**.

Public Opinion

Although the movement is still in its infancy, there is clearly momentum in the United States toward expanded medical access. One driver of this momentum is public opinion. A 2023 poll conducted by the UC Berkeley Center for the Science of Psychedelics found that 61% of voters supported legalising regulated, therapeutic use of psychedelics.

The same poll found much higher levels of support among voters who had personally used psychedelics or were close to somebody who had. This result suggests a positive feedback loop: as more states legalise therapeutic use of psychedelics, and use becomes more com-

mon, more people will have first- or secondhand experience with the drugs. Greater familiarity will likely lead to increased public support.

3.2 Legislative Routes to Wider Access

State Legalisation of Psychedelic Therapy

At present, outright legalisation of psychedelic medicine is unlikely to materialise in most states. Many state legislatures are actively considering bills to legalise psychedelic-assisted therapy, however.

Direct democracy mechanisms, such as ballot initiatives and referenda, seem to be a more promising route than relying on state legislatures to achieve medical legalisation. The two states that have legalised psychedelic therapy, Oregon and Colorado, both did so by ballot measure, and Massachusetts voters considered a similar ballot initiative on 5 November 2024, which was rejected. See **1.1 Primary Laws and Regulations**. This trend is unsurprising: as mentioned in **3.1 Access to Psychedelic Medicines Today**, the majority of American voters believe that psychedelics should be legalised for medical use. Democratic voters are especially open to legalisation. Future movement toward legalisation of medical psychedelics is therefore most likely to occur via ballot initiatives in blue states (as was the case for medical cannabis). With that said, certain red states, including Utah and Indiana, are also at the forefront.

Expanding Research

If there is one priority that both proponents and critics of psychedelic legalisation can agree on, it is the need for more research. Although the federal government and most states are hesitant to legalise psychedelic medicine, policies to facilitate or fund basic research have been much more successful, as discussed in **3.1 Access to Psychedelic Medicines Today**.

The federal government has the power to expedite research into Schedule I substances, like psychedelics, by reforming the CSA's labyrinthian permitting process. In 2022, Senators Cory Booker (D-NJ) and Rand Paul (R-KY) attempted to do so by sponsoring S.B. 5123, the Breakthrough Therapies Act. But this bill died in committee and never reached the Senate floor. If Congress eventually succeeds at amending the CSA and streamlining research into Schedule I drugs, that will accelerate the wave of medical research already being promoted at the state level.

The federal government could also facilitate research into psychedelics by establishing a research programme under the Office of the US Attorney General. 21 U.S.C. § 872(a) authorises the Attorney General to "carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs". The Attorney General could use this provision to initiate new psychedelic research programmes and to protect existing ones from the threat of legal sanctions, promoting greater understanding of the risks and benefits of these unique substances.

Changes to Federal Policy

In addition to enabling research, the federal government could expand access to psychedelic medicine in other ways. Full legalisation of psychedelics at the federal level seems unlikely at present. But even minor federal policy changes could facilitate greater shifts at the state level.

For example, DOJ could signal that it will not interfere with states that choose to legalise medical psychedelics. Such an announcement could parallel the Justice Department's 2013 Cole Memo, discussed in **2.1 Common Cross-Jurisdictional Issues**. The Cole Memo gave states reassurance that they would not be the target of

capricious federal enforcement of the CSA as to cannabis, and it provided valuable guidance for state regulatory regimes. DOJ could signal a similar hands-off approach to embolden states to experiment with psychedelic policy.

Other federal actions would also likely encourage state governments to move toward legalisation, such as FDA approving the use of psychedelics for medical purposes, or DEA reclassifying them to a lower schedule. Colorado, for example, has passed a bill that would automatically legalise MDMA-assisted therapy in the state as soon as it is federally legalised and approved by FDA. Arizona has passed a similar bill relating to workers' compensation for MDMA-assisted therapy. See **1.1 Primary Laws and Regulations**.

Focus on Military and First Responders

Veterans, active-duty military personnel, and first responders suffering from PTSD, depression, and other mental health issues are a highly sympathetic group. Legislatures have therefore been willing to grant these individuals greater access to medical psychedelics than the general public.

For example, in 2023, Congress voted to fund research of psychedelic therapy on active-duty military and veterans suffering from PTSD and depression. Similarly, several states, including Texas, Indiana, and Massachusetts, have passed legislation allowing medical research on psychedelics for veterans and first responders specifically. Virginia is considering a similar law.

Laws permitting medical psychedelic use by veterans, military, and first responders will allow higher-quality research on the drugs' effects. Depending on results, this could be a stepping stone to broader access in the future.

3.3 Adult-Use Markets

The Likelihood of a Regulated Adult-Use Market

Although the regulated medical use of psychedelics may not be far off, a legal market for psychedelics for recreational or non-indigenous spiritual purposes is far less likely in the near term.

The American public, although supportive of legalising medical use, is still skeptical of allowing use for other purposes. A 2023 poll conducted by the UC Berkeley Center for the Science of Psychedelics found that only 43% of voters supported legalising psychedelics for spiritual or religious use (beyond the narrow exception for indigenous use already included in the CSA, see **2.2 How Access is Affected by Foreign Law and Regulation**). If the question had been asked about recreational use, the approval rate would presumably have been lower.

Thus far, no state legislature has even considered a bill that would outright legalise commercial sales of psychedelics for non-medical use.

Decriminalisation

A potential half-measure on the way to an adult-use market is decriminalisation. Decriminalisation is a far cry from a legal, regulated market. Even in states and cities that have decriminalised psychedelics, the drugs may not be legally sold, and users must resort to the illicit market to obtain them. However, individuals in those jurisdictions will no longer be prosecuted merely for possessing and using psychedelics.

Many state legislatures have considered decriminalisation of psychedelics. However, only Oregon and Colorado have actually done so, and Oregon later reversed course. In 2020, Oregon voters approved Ballot Measure 110, which eliminated criminal penalties for possessing

personal amounts of all controlled substances. But in 2024, due to concerns about the state's fentanyl crisis, this measure was repealed by the state legislature.

Colorado, via Proposition 122 in 2022, decriminalised personal use and possession (but not sale) of several naturally occurring psychedelics: DMT, psilocybin, mescaline and ibogaine. Colorado is currently the only state in which individuals may possess and use psychedelics recreationally without criminal penalties.

Even in states that have not decriminalised psychedelics, some city governments have decided to deprioritise enforcement of laws prohibiting psychedelic possession. Jurisdictions that have unilaterally decided to decriminalise psilocybin or other psychedelics include Denver, CO; Oakland, CA; Santa Cruz, CA; Berkeley, CA; San Francisco, CA; Ann Arbor, MI; Detroit, MI; Seattle, WA; Olympia, WA; and the District of Columbia, among others.

It is possible that other states or cities could decriminalise psychedelics in the near future: in the November 2024 election Massachusetts had a ballot initiative to legalise therapeutic uses of psychedelic substances (failing but garnering 42.9% of the vote), and California lawmakers voted to decriminalise psychedelics in 2023 (though the bill was vetoed by Governor Gavin Newsom).

On the other hand, Oregon's failed experiment with drug decriminalisation has likely dampened enthusiasm for such measures. Even Measure 110's advocates acknowledge the increase in overdose deaths and homelessness that occurred in Oregon after 2020. It remains an open question whether this surge was caused by decriminalisation, or by external factors such as the wave of fentanyl hitting the market around the same time. But politicians and pundits who favour stricter drug laws have been quick to point to Oregon as a cautionary tale.

Cannabis as a Model for Psychedelic Legalisation

If there were a legal adult market for psychedelics, what might it look like? An obvious analogue is the legal recreational cannabis markets that have been established in dozens of US states.

In states that have legalised recreational cannabis, cannabis may only be sold to individuals 21 and older by state-licensed and regulated dispensaries. These dispensaries must verify the age and identity of their customers and may only sell a limited quantity to each customer. Growers of cannabis must comply with rigorous reporting and testing requirements. Generally, it is illegal for individuals to consume cannabis in public. It is likely that similar rules would govern a legal psychedelic market if one ever emerged.

Cannabis also illustrates the pathway psychedelics might take from criminalisation to legality. In 1996, California became the first state to legalise cannabis for medical use, with several other states quickly following suit. However, it was not until 2012, when over a dozen states had legalised medical cannabis, that Colorado and Washington became the first states to establish legal recreational markets.

Similarly, states may begin to consider legalising the recreational use of psychedelics once medical use is widespread and the safety of the drugs is better established. But in the next decade, policy changes will probably remain limited to medical legalisation and decriminalisation.

Trends and Developments

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Perkins Coie has represented clients at the forefront of technological change for more than a century, from aviation to artificial intelligence. Its practice of law is enriched by its deep understanding of its clients' businesses and the industries in which they compete. Like its clients, the firm looks forward to new possibilities and frontiers with unwavering intellectual curiosity. With 21 offices in the United States, Asia, and Europe – and a network of law firms around the world – Perkins Coie assists clients anywhere and everywhere they do business. The firm's cannabis law team, which includes former federal prosecutors and experienced litigators, offers distinctive skill sets in an industry rife with legal challenges. It identifies and proactively addresses issues exacerbated by a complex patchwork of local, state, and federal laws. Perkins Coie has represented many of the world's largest brands in cannabis-related matters.

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Informing Psychedelic-Assisted Therapy Policy: Lessons Learned from Cannabis

Introduction

Marijuana is state-legal and highly regulated in 38 state medical markets and 24 adult-use markets. In those states, people can readily purchase marijuana from state-sanctioned marijuana dispensaries. The commercial products sold in those dispensaries are subject to rigorous standards, including mandatory age verification, product testing, marketing restrictions, and specific packaging and labelling requirements.

Over the past decade, the marijuana industry has continued to work out the kinks inherent in any newly regulated industry. While the marijuana and psychedelics industries have their marked distinctions – for example, no state is proposing a commercial market for psychedelics, and there is thus no need to decriminalise psychedelics – there is still much that states considering psychedelics reform could learn from pioneers in the state-regulated marijuana industry. The burgeoning psychedelic industry should take a page from the book of the marijuana industry to ensure that it does not repeat the marijuana industry's identifiable mistakes and also so that it can more directly replicate the marijuana industry's successes. Of course, one of the more significant obstacles that the state-regulated marijuana industry faces is competition from the illicit market and synthetic hemp-derived cannabinoids.

The experiences of Colorado and Oregon in pioneering marijuana legalisation offer valuable insights for the emerging psychedelics industry. Colorado Amendment 64 passed on 6 November 2012, and led to the legalisation of adult-use marijuana in December 2012. State-licensed retail sales began in Colorado in January 2014. In November 2014, Oregon became the fourth state to legalise adult-use marijuana. Suffice it to say that Colorado and Oregon paved the way for marijuana legalisation and state regulation. Colorado and Oregon are once again leading the way in the emergence of the state-regulated psychedelics industry. Oregon rolled out its psychedelic-assisted therapy (PAT) programme in May of 2023, and Colorado is expected to fully launch its PAT programme in January of 2025. There are no other states that have legalised PAT, though Massachusetts is commencing a ballot initiative in November 2024.

Below, we describe some of the speed bumps that the marijuana industry has faced, with particular attention paid to those that can serve as guideposts for psychedelics. We also tackle some of the more pervasive areas ripe for industry collaboration and information sharing.

First, a Disclaimer: The Cannabis Pathway Is Not the Panacea for Psychedelics

There are now 38 state medical markets and 24 state adult-use cannabis markets nationwide. In contrast, state-regulated psychedelics industries currently exist only in Oregon and Colorado. No other states have legalised PAT, though Massachusetts is commencing with a ballot initiative in November 2024 and other states are sure to follow. While these states' psychedelics programmes can and should be informed by lessons learned in state-regulated marijuana industries, the significant differences between marijuana and psychedelics mean that the cannabis pathway is not the panacea for psychedelics.

Many interested in psychedelics reform are actively basing their strategies on the cannabis movement's playbook: ignoring federal prohibition and forging ahead with state-level decriminalisation laws that assume the federal government will not attempt to enforce federal laws to

shut down or interfere with their programmes. This is a mistake for several reasons. First, psychedelic drugs are very different substances to cannabis. As a group, they have a far more dynamic risk profile. The altered mental state that psychedelic experiences induce can leave users vulnerable. Many also leave users under the influence for far longer periods of time. As a result, the risk of adverse events and even victimisation while in that altered state are far higher than is the case with cannabis. There are also many different psychedelic substances, and not all of them are as well understood as cannabis is. This creates even more risks for users who take state decriminalisation laws as a certification of safety for use.

Second, psychedelics' medical utility differs drastically in terms of its scope of potential and mechanism of action. While cannabis undoubtedly does have important medical uses, psychedelics have shown immense early promise in treating the conditions driving the US's current and seemingly intractable overdose and mental-health crises. FDA has granted psilocybin double breakthrough therapy status for its promise in treating treatment-resistant depression and PTSD. MDMA has achieved breakthrough therapy status for its ability to treat PTSD. In addition, FDA recently designated LSD as a breakthrough therapy for generalised anxiety disorder. Given the scale and severity of the mental health crisis currently facing the US, strategies that might delay the essential federal reforms necessary to make PAT available and affordable nationwide are ill-advised.

Since PAT works through the combination of a psychedelic drug and psychotherapy, it presents regulatory obstacles that find no analogue in cannabis or traditional pill-a-day pharmaceutical drugs. While FDA generally regulates the drug part of that equation, it does not have the authority to regulate psychotherapy, an area traditionally left to state oversight. Bringing these treatments to market in a responsible way will require state and federal co-operation in a way that cannabis simply does not.

Third, because psychedelic drugs have a more dynamic risk and benefit profile than cannabis, there is a heightened need for health care professional supervision in their administration if they are to achieve their full potential.

Fourth and finally, the cannabis industry's continued existence depends entirely on the unstable truce the state and federal governments have hammered out over the decades. Today, that truce has been formally embodied in DOJ enforcement guidance that ensures prosecuting cannabis crimes at the federal level is a low priority and rarely becomes an issue for state-level operators. In addition, appropriations riders bar DOJ from spending appropriated funds to interfere with state medical cannabis markets. None of these things exists for psychedelics, and it is therefore a mistake to assume that the federal government will turn a blind eye to similar activity under state-regulated psychedelic programmes. Indeed, DEA has already begun taking a more active role in investigating violations of the Controlled Substances Act (CSA) involving psychedelic substances. For these and other reasons, those interested in effective psychedelics reform must think outside and beyond the cannabis playbook.

Lesson One: Protecting Consumers Through State Regulation

Psychedelic "legalisation" bills from around the country are essentially divided into three buckets: (i) PAT, (ii) research, and (iii) decriminalisation bills. While there are no states currently con-

templating a commercial retail marketplace for psychedelics, there are nonetheless two states currently allowing the sale of psychedelics to trained facilitators for the purposes of holding PAT sessions. Colorado is allowing home growing of psilocybin and the gifting of psychedelics without remuneration.

The psychedelic industry should take note of lessons learned by the marijuana industry to protect consumers. In the marijuana industry, there are intrastate commercial sales in 38 state medical markets. Those markets are governed by state regulators in each jurisdiction. While regulations vary from state to state, there are many similarities across the board. Those parallels could be helpful for those states contemplating how to regulate psychedelics.

For instance, each state requires age verification, laboratory testing, packaging, and labelling to meet state safety standards and technology to track sales and prevent diversion. Simultaneously, two unregulated markets are competing for airtime. The illicit market has been alive and well for decades. According to economists, the illicit market accounts for approximately USD60 billion in sales revenue annually (the state-regulated market accounts for about USD38 billion). Those products share none of the consumer protections offered by the state-regulated market. There is also an unregulated and synthetic hemp-derived intoxicating cannabinoid industry flourishing nationwide by selling intoxicating hemp cannabis products in interstate commerce without any consumer protections. These products could contain nickel, palladium, other heavy metals, pesticides and dangerous chemicals. Because they are not subject to mandatory testing, using these drugs is like playing full-body Russian Roulette. Many of those products are also packaged in containers replicating children's candy brands. And none have mandated age-verification requirements, notwithstanding their potential toxicity or intoxicating properties. That industry boasts about USD28 billion in annual sales revenue.

The psychedelic industry not only needs to make certain that products being used during assisted therapy sessions are safe, but regulators also need to make sure that illicit market products are inaccessible, particularly to minors. That translates into employing mandated product standards for consumer safety and perhaps tracing technology to protect from diversion. State legislatures and regulators should also leverage traditional law enforcement resources to crack down on underground markets. While law enforcement agencies have limited resources, and polling suggests that most people believe that most drugs should be decriminalised or even legalised, there is danger in ignoring unlawful psychedelic markets. In marijuana, law enforcement has decided that diverted and illicit marijuana enforcement is not a high priority. While that may seem logical from a resource and public policy standpoint, it is the opposite and quite antithetical to reason. The only way to keep the public safe is to allow for the provision of safe, tested, regulated products. And that means supporting the state-regulated market while cracking down on the illicit market. Once states decide to allow psychedelic programmes, they must pay close attention to the dangers of an illicit market and potentially dangerous products that could contain pesticides, heavy metals, or worse. States should consider robust protections for any regulated market created and enforcement actions against illicit operators. It will be the key to protecting consumers, especially for psychedelic consumables.

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Lesson Two: Learning From the Failures of Social Equity Programmes

In the marijuana industry, most states have set-asides for social equity licensees. That preferential treatment for people of colour who have been negatively affected by the war on drugs had the best of intentions but has not proven to materially increase licensure for disenfranchised communities.

The PAT industry is making efforts to engage with Indigenous communities, include Indigenous persons on its boards, and make sure that spiritual practices are enshrined and protected in state law. States are also making efforts to keep costs down so that access is not limited to people of wealth. Those are all worthy efforts, but more needs to be done to make certain that Indigenous persons and people of colour not only have access to PAT but also have access to opportunities to become a facilitator, manufacturer or host property licensee.

State psychedelic regulators would benefit from collaborating with state marijuana regulators to learn from prior mistakes and forge their own path. For instance, while the state of New York had the best of intentions, its execution of social equity programmes was arguably an objective failure. In Arizona, critics have complained that too much revenue wound up being siphoned for policing and not enough monies were dedicated up front for social equity licensees. Minnesota, on the other hand, is an outlier. That state specifically earmarked monies for these purposes. Before the psychedelics industry gets too far down the path, it would behoove state regulators to learn from those who came before them.

Lesson Three: Avoiding the Ubiquitous and Perilous Lab Testing Issues of the Marijuana Industry

The state-regulated marijuana industry has seen repeated inaccuracies with lab testing results depicting the wrong cannabinoid content, incorrect levels of heavy metals, pesticides, or other harmful additives, or labels that do not accurately reflect what is being sold to consumers in nearly every state with a regulated programme. Some of the criticism levelled in the cannabis industry relates to regulatory incompetence, where states have incentivised cheaters with lethargic investigations and enforcement actions without teeth (eg, only initiating small fines). Some states seemingly aren't following through on implementing "secret shopper" programmes, where non-abiding products are pulled from the shelves by state investigators. Synthetics products are represented as "natural", notwithstanding contaminants and processing techniques that are far from "natural". Of course, the majority of adverse events in the regulated marijuana industry are largely attributable to synthetic cannabinoids derived from hemp (delta-8 THC).

All of these irregularities must be avoided in psychedelics, but comparisons to the psychedelics industry may not be apples-to-apples. For instance, potency inflation is a major problem in cannabis because many consumers are looking for high-THC products. However, in psychedelics, it is more important that levels of psilocybin or psilocin are accurate, as precise dosing is key to a successful experience. Potency inflation should be a non-issue in psychedelics. Still, it will be critically important to stay on top of accuracy. State psychedelic regulators must also be intellectually curious and seek out appropriate criteria for determining harmful by-products. In cannabis, there are tolerated levels of solvents, pesticides, heavy metals, bacteria, yeast, mold,

mycotoxins, and residual solvents. But in psychedelics, there are likely different considerations for pollutants. The psychedelic industry needs to learn from commonalities in cannabis but also pay close attention to the unique differences.

Lesson Four: Avoiding the Barriers in Conducting Research

In testimony before the House Subcommittee on Health, Committee on Energy and Commerce, Dr Nora Volkow, the Director of the National Institute on Drug Abuse, recently described the extraordinary challenges researchers face when seeking to study Schedule I substances, contrasting them with the dramatically more relaxed regulations that apply to substances in Schedules II-V:

"Even experienced researchers have reported that obtaining a new Schedule I registration [from DEA under 21 U.S.C. 823(f)], adding new substances to an existing registration, or getting approval for research protocol changes is time consuming. Unlike for Schedule II through V substances, new and amended Schedule I applications are referred by the DEA to the HHS for a review of the protocol and a determination of the qualifications and competency of the investigator. This review is often in addition to other reviews of the proposed research and investigator, such as the federal grant review process, the FDA Investigational New Drug (IND) application review process, and Institutional Review Board and Institutional Animal Care and Use Committee reviews. Establishing the security infrastructure needed to conduct Schedule I research can be expensive and may need to be duplicated for each registrant working within a single research department. Researchers have also reported that there is a lack of clarity in some of the registration requirements and variability in their interpretation, which complicates and adds time to the process. For example, researchers report inconsistency in the guidance they have received on whether one individual can work under the registration of another, whether separate registrations are needed for each of an investigator's research sites within the same campus, whether a manufacturing registration is needed to create final dosage formulations for research purposes, among other issues. Researchers have reported that sometimes these challenges impact Schedule I research and deter or prevent scientists from pursuing this critical work."

A paper published by the National Library of Medicine in 2017 examined the problem of Schedule I research barriers in the cannabis context. After describing "[t]he substantial layers of bureaucracy that emerge from cannabis's Schedule I categorization", the authors explain that Schedule I classification stifles "research on the health effects of [drugs]... in the United States, leaving patients, health care professionals, and policy makers without the evidence they need to make sound decisions regarding the[ir] use...". Their conclusion is as ominous as it is indisputable: "This lack of evidence-based information on the health effects of cannabis and cannabinoids poses a public health risk."

Beyond the restrictions Schedule I itself places on science and research, there is also a deeper incentives problem blocking the laboratory door. In the US, money – and more specifically, pharmaceutical industry profits – drives scientific research and understanding of drugs. Congress has made it impossible to bring a drug to market without doing the research necessary to obtain FDA approval. Doing the scientific research necessary to run the FDA-approval gauntlet usually costs around USD1 billion. Pharmaceutical companies are willing to foot that extraordinary bill to bring drugs to market because once they

get FDA approval, they also get years of market exclusivity. Without that temporary monopoly and various intellectual property rights, they would never be able to recoup their investment and thus would never have an incentive to pay for the research in the first place. In other words, it makes sense to pay the price for FDA approval to bring a drug to market before there is a market for the substance. With Schedule I psychedelics, however, there is already a booming interstate market for them. Few drug companies (or anyone else) are willing to pay a billion dollars to prove a drug is safe and effective for marketing when it is already on the market.

The result is a Kafkaesque nightmare loop for those seeking to establish the safety and efficacy of psychedelics on the federal government's terms. The more people use these substances across the country, the more urgency there is to study them. At the same time, however, because people are using the substances widely before the research has taken place, the government insists that everyone is abusing them, which, by the government's "logic", only reinforces the need to keep them in Schedule I and not let anybody study them.

Making it harder to study the drugs because people use them is perverse and dangerous, but that is, in fact, precisely what Schedule I classification does. As a result, if scientific understanding of psychedelics is to flourish, reform advocates must secure rescheduling.

Lesson Five: Managing Interstate Commerce and the Food, Drug, and Cosmetic Act

Cannabis companies have found themselves on the wrong side of FDA warning letters for producing edible, intoxicating products that violate the Food, Drug and Cosmetic Act (FDCA). Many of these products were sold in interstate commerce, direct-to-consumer, and without lab testing or age verification. Many also have product packaging that inappropriately appeals to children, as prohibited by state marijuana regulations. The responsible psychedelic industry could take a page from the cannabis industry and make certain that any products being sold follow strict standards. Any products that don't follow those standards should be removed from commerce.

For example, FDA and the Federal Trade Commission issued warning letters to five companies in July 2024 for illegally selling copycat food products containing delta-8 THC, an intoxicating cannabinoid. The copycat products imitated well-known consumer brands. As FDA put it, this type of labelling "can result in children or unsuspecting adults consuming products with strong resemblance to popular snacks and candies", leading to unintentional ingestion and overconsumption that could pose considerable health risks. The agencies' announcement noted concerns with how easily young people could access these intoxicating products as well as impurities or variations in product composition, which could result in harm or have unpredictable effects on consumers. A responsible psychedelic industry would ensure that intoxicating products are sold in compliance with applicable law. Namely, intoxicating psychedelic products would be available only with appropriate age verification and marketing that does not advertise to children.

More broadly, FDA has concluded that interstate commerce in food products containing THC is prohibited under the FDCA for two reasons.

- First, under the agency's food additive requirements, any substance intentionally added to food is a food additive and,

therefore, subject to pre-market review and approval by FDA, unless the substance is generally recognised as safe (GRAS) by qualified experts under the conditions of its intended use, or the use of the substance is otherwise excepted from the definition of a food additive. See 21 U.S.C. § 321(s) and § 348. In December 2018, FDA concluded its evaluation of GRAS notices related to three hemp seed ingredients – hulled hemp seed, hemp seed protein powder, and hemp seed oil. The agency had no questions regarding the company's conclusion that using such products as described in the notices was safe. Outside of these three hemp seed ingredients, cannabis ingredients in food products would violate the agency's food additive regulations.

- Second, under the drug preclusion provision of 21 U.S.C. § 331(ll), it is generally prohibited to introduce or deliver for introduction into interstate commerce any food to which has been added a substance that is an active ingredient in an FDA-approved drug product or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. Among other things, THC is an approved drug product in multiple drugs, such as Marinol and Syndros, and the existence of substantial clinical investigations has been public for some time.

FDA's food additive and drug preclusion requirements would likely similarly apply to food products containing psychedelics. As a result, the introduction of food products containing psychedelics in interstate commerce would violate the FDCA.

Lesson Six: Considering the Dormant Commerce Clause

The evolving dynamic between state regulation of the cannabis industry and the federal legislature's exclusive jurisdiction to regulate interstate commerce also provides helpful lessons for the psychedelics industry. This dynamic centres around the Dormant Commerce Clause, the constitutional doctrine that limits states' ability to impose regulations that interfere with interstate commerce. The Dormant Commerce Clause prohibits, for example, state regulations of "economic protectionism" that facially or effectively discriminate against out-of-state parties.

Because cannabis is a controlled substance that is illegal to produce, sell and distribute at the federal level, there is no interstate cannabis market. Rather, each state's cannabis industry operates exclusively within that state. Despite this fact, most federal courts that have considered challenges to state regulations that burden out-of-state players in the cannabis industry have held that such regulations are impermissible under the Dormant Commerce Clause. These courts have therefore, necessarily determined that the Dormant Commerce Clause's prohibition against state regulations that burden non-residents' participation in an industry does not depend on whether that industry unequivocally has an interstate reach.

The same application of the Dormant Commerce Clause can be expected in future challenges to state regulation of psychedelics generally, which are also illegal to produce, sell, and distribute at the federal level but may be subject to state regulation that either facially or effectively discriminates against out-of-state industry players. This application will be complicated by the fact that states' regulation of psychedelics will be tied to the use of those psychedelics in a

therapeutic setting. States can impose licensing requirements for psychotherapists without running afoul of the Dormant Commerce Clause; it remains to be seen how the imposition of similar licensing requirements for the practice of PAT will withstand legal scrutiny.

Another layer of the Dormant Commerce Clause's bearing on the cannabis industry is in its move toward federal legalisation or rescheduling. Because each state's cannabis industry is insular within the state, there are over three dozen states with differing regulations for medical and/or recreational cannabis use. When cannabis is inevitably rescheduled and federal legislation is passed that regulates the cannabis industry on a national level, concerns over the viability of state regulations in light of the Dormant Commerce Clause will only increase. This is a problem for each state's wholly intrastate cannabis industry, which is built around the state's regulations at great expense. But there is a solution: the federal legislature can authorise activity that would otherwise run afoul of the Dormant Commerce Clause by taking action that makes it "unmistakably clear" that the Dormant Commerce Clause does not apply in a particular context.

Thus far, bills proposed in Congress regarding cannabis legalisation and rescheduling have not made "unmistakably clear" that state cannabis regulations would still apply alongside federal regulations despite the Dormant Commerce Clause; granted, those bills have not become law. Still, the cannabis industry and the psychedelics industry should both be mindful that the regulations around which those industries have heretofore been built may change, perhaps even dramatically so, if federal legislation regulating cannabis is passed that fails to make the viability of state regulations "unmistakably clear".

Lesson Seven: Bearing Section 280E's Harsh Tax Penalty

Section 280E of the Internal Revenue Code forbids businesses "trafficking" in Schedule I or II substances from deducting ordinary business expenses from gross income. See 26 U.S.C. § 280E. The upshot of Section 280E is that the only deductions available to a business trafficking in Schedule I or II controlled substances are the costs of goods sold (COGS) and deductions attributable to a separate and lawful trade or business. COGS are the direct expenses incurred to make goods or services. They do not include other expenses, like advertising expenses, rent, salaries and more.

This harsh tax penalty has hobbled the cannabis industry. According to a recent analysis, the industry paid USD1.8 billion in 280E tax in 2022, and some cannabis companies pay unsustainable 80% tax rates. The result is a Hobson's choice between raising prices beyond what most customers will pay or going out of business. While the cannabis companies that have not yet gone out of business have obviously chosen the former, they are left to fight against a thriving illicit market that undercuts their prices with ease. This, by the way, is precisely what Section 280E was designed to do – make it virtually impossible to sustain a business trafficking in Schedule I or II substances.

Without rescheduling to Schedule III or better, any would-be "psychedelics industry" is destined to walk headfirst into the same Section 280E woodchipper. In fact, Section 280E could be even worse for psychedelics operators because there are more services involved in the provision and administration of psychedelics than cannabis. There is a reason Oregon calls them psilocybin service centres, after all. Since the cannabis industry is comparatively more

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heavily weighted toward goods as opposed to services, psilocybin operators may face even greater exposure to Section 280E's deadly glare.

Lesson Eight: Pursuing Rescheduling

As alluded to throughout this article, the federal legalisation of marijuana through rescheduling is now seemingly an inevitability and bears on virtually every legal consideration regarding marijuana today. The rescheduling process began in earnest in October 2022, with President Biden's request that the Department of Justice and the Department of Health and Human Services (HHS) initiate an administrative process to review whether marijuana is appropriately classified under federal law. After conducting that review, HHS concluded that marijuana should be rescheduled from Schedule I to Schedule III because of its lower potential for abuse and dependency issues. DEA subsequently scheduled an administrative law judge hearing for 2 December 2024, for rulemaking on this potential rescheduling.

Like with marijuana, the rescheduling of psychedelics is of central importance in the emergence of the psychedelics industry. However, the differences between marijuana and psychedelics suggest that the process for rescheduling psychedelics will unfold differently. Because of marijuana's lower potential for abuse and dependency issues, there are booming state markets for recreational marijuana use that make rescheduling marijuana from Schedule I to Schedule III the most logical course of action. Unlike with marijuana, states are not currently contemplating the regulation and decriminalisation of the recreational use of psychedelics, meaning there is not the same obvious imperative to reschedule psychedelics from Schedule I to Schedule III. Additionally, the use of psychedelics involves distinct health and safety risks that make immediate rescheduling to Schedule III less viable.

One path forward is to reschedule psychedelics from Schedule I to Schedule II to promote greater research into the therapeutic uses of psychedelics without the emergence of a nationwide recreational market. Indeed, Dr Sunil Aggarwal, medical doctor and fellow of the American Board of Physical Medicine and Rehabilitation, American Academy of Hospice and Palliative Medicine, has been engaged with DEA regarding his petition to transfer psilocybin from Schedule I to Schedule II considering its benefits in treating terminally ill patients. DEA has yet to reschedule psilocybin to Schedule II, but efforts such as Dr Aggarwal's will surely advance the process in the interest of more effective regulation of psychedelics.

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