The Report on Psychedelics

VOLUME II

PRIMARY PSYCHEDELIC DRUGS

Presented by the NEO Exchange

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Foreword

BY JOS SCHMITT

In an age when addiction, mental illness, and psychological disorders are more prevalent than ever, finding new and effective treatments has become mission critical. Psychedelics offer a huge source of hope for millions of people around the world.

Although research into psychedelics has been ongoing since the late 19th century, real progress was interrupted during decades of bans, prohibitions, and social stigma based on misinformation. But the tide is turning. Researchers, public health authorities, governments, and - critical to long-lasting success - investors have turned their attention back to this promising pharmaceutical market and psychedelics is at the cusp of becoming a true growth industry, delivering value to the investor community and society at large.

Education, research, development, and testing are imperative for bringing new treatments to market, and Canada is among the countries that are leading the way. As Canada's next-generation stock exchange with an unwavering commitment to innovation, NEO Exchange was proud to list MindMed as the world's first publicly traded psychedelics inspired neuro-pharmaceutical company, on March 3, 2020. With noteworthy investors backing the company, including Kevin O'Leary of Shark Tank fame, and a singular focus on developing breakthrough medicines to treat an array of addictions and mental illnesses, MindMed is at the forefront of this revolutionary industry, garnering worldwide media attention and poised for tremendous growth over the years ahead.

With many more companies emerging in the psychedelics space, NEO is committed to helping them raise capital through its leading-edge private placement platform, and when ready, hosting those companies on its stock exchange where fairness, liquidity, efficiency, and service are the driving forces.

From day one, we've done things differently at NEO by living innovation while always staying true to our values of doing what is right for capital-raising companies and investors. The psychedelics space shows incredible promise and NEO is ready and willing to help bring that potential to fruition. Great opportunity lies ahead - this is about doing what is right for everyone!

JOS SCHMITT
PRESIDENT & CEO
NEO EXCHANGE

Preface

The marketplace for and science of psychedelic drugs is inherently complex—and potentially perplexing—for the average consumer. This is understandable based on the sheer variety of chemicals of interest that psychedelics encompass and the wide variety of for-profit and not-for-profit organizations around the globe that it attracts.

This Report provides an overview of seven of the most common psychedelic drugs in terms of their origination, effects, potential efficacy in treating conditions and research being conducted. (Of technical note is the fact that some organic compounds can be replicated synthetically.)

Regardless of their motive or impulse for using these controversial and stigmatized drugs, an individual consumption episode/experience is called a "trip." A trip is commonly defined as "an intense visionary experience." The visionary part of the definition references the hallucinations that are common among most, but not all, psychedelic compounds when ingested by humans. Beyond hallucinations, users sometimes experience a complex and difficult-to-describe intermingling of senses, such as "hearing light and seeing noise" that's often accompanied by extreme emotions and alien sensations.

The world of psychedelic drug trips is sometimes so unusual, especially for those who have never experienced them, that one of the main challenges becomes the subjective articulation of the experience itself. While often perceived as stressful or disorienting, more experienced users of psychedelics often report a cessation of anxiety or fear and an ability to introspectively release one's ego, an exercise that is credited with helping some patients deal with conditions related to trauma, such as severe anxiety and depression and PTSD.

Entheogenic vs. Synthetic Drugs

Entheogenic plants are defined as those yielding one or more chemical substances that, when ingested by humans, produces a "nonordinary state of consciousness for religious or spiritual purposes."[1] For the purpose of this Report, the entheogenic plants surveyed include ayahuasca, DMT, ibogaine, and psilocybin.

Synthetic psychedelic drugs, on the contrary, are those that are construed in a laboratory setting that achieve the same results as their entheogenic cousins. The synthetic psychedelic drugs covered in this Report include ketamine, lysergic acid diethylamide (LSD), and methylenedioxymethamphetamine (MDMA). DMT can be obtained via extraction from a plant or synthesized in a lab.

1 According to research publisher ScienceDirect.

Medicinal Efficacy

As a group, the psychedelic drugs covered in this Report offer some common and sometimes overlapping benefits in terms of their potential use in various medical and wellness therapies. Psychedelic assisted psychotherapy is being investigated to treat serious and life altering mental health conditions. Another line of inquiry is being conducted into the effectiveness of removing the psychoactive component of a psychedelic substance to treat a range of health disorders. Pain management, substance abuse and neurological disorders like cluster headaches are all showing promise as being able to be treated by psychedelic substances in various forms of delivery.

Safety Profiles

Researchers discuss the potential negative side effects of any drug in terms of its safety profile. For psychedelic drugs, these profiles tend to feature common undesired effects, such as panic attacks, anxiety, delusions, confusion or disorientation, and paranoia. Consumers of psychedelics who are not given proper guidance and education regarding the expected efficacy of the drugs they are consuming are more likely to experience a "bad trip" or not gain the maximum benefit from these powerful substances.

Legal Status

The drugs covered in this Report range from decriminalized in certain jurisdictions to the most restricted and controlled categories (under the definitions of the United Nations and the United States), Schedule I. Most psychedelic drugs fall within Schedule I, with their creation, distribution, and consumption prohibited and often carrying harsh criminal penalties.

Ayahuasca

Ayahuasca, also known as ayaguasca and aioasca, is a traditional tea that has been in use for at least a millenia in various Amazonian cultures of South America. Despite its ancient roots, this psychedelic elixir is incorporated into religious and spiritual rituals to this day. The exact discovery and origin of the ritualistic use of the powerfully mind altering effects of ayahuasca are unknown. The core psychoactive chemical within this brew is N,N-Dimethyltryptamine, or DMT.

Characteristics & Distinctions

Ayahuasca tea is a bitter beverage that sometimes manifests as a black sludge known in Peruvian cultures as "La Purga." It is brewed using two plants: The leaves from a shrub called chacruna (Psychotria viridis) and the stalks of the ayahuasca vine (Banisteriopsis caapi)--both of which, in proper doses, can convey hallucinogenic properties. Ayahuasca tea trips feature a bioavailability onset period of 20-60 minutes, with a duration of two to six hours.

It is chacruna that contains the molecule DMT that is sought for its hallucinogenic prowess. The vine ayahuasca, however, contains MAO inhibitors (which interfere with an enzyme in the body to prevent the breaking down of a chemical compound) without which the DMT would merely be metabolized (digested) in the liver and gastrointestinal tract (by MAOs). Without the ayahuasca vine's properties, the DMT delivered by the chacruna shrub would never become active in the bloodstream to deliver its strong psychotropic efficacy, including hallucinations and enhanced emotions.

Like sometimes occurs during consumption of psilocybin mushrooms, ayahuasca evokes vomiting, a characteristic that has been woven into the traditional ceremonies of many Amazonian cultures.

Legal Status

In most jurisdictions ayahuasca itself resides in a legal grey zone. Ayahuasca tea is not, formally or specifically, prohibited. However, because it contains a Schedule I drug, DMT, its use is restricted in many nations.

In the United States, those employing ayahuasca tea during the course of a religious or spiritual ritual or ceremony that is affiliated with an official church are legally permitted to consume ayahuasca tea (consumers must be church members to achieve legal status). Similar exemptions exist in Canada.

Decriminalization

Ayahuasca has been decriminalized in Oakland CA and Santa Cruz CA.

Approvals

No relevant approvals for ayahuasca.

Studies and Trials

Total Studies	1
Total Active Studies	0
Total Complete Studies	1

Breakdown of Active Studies (Active, Recruiting, Pre-Recruiting)

Study Phase	Number of Studies	Prominent Conditions Studied
Phase I	0	n/a
Phase II	1	Major depression

Notable Studies

Phase 2 clinical trials have been conducted for ayahuasca with respect to treatment-resistant depression by the Universidade Federal do Rio Grande do Norte in Lagoa Nova, Brazil.

N,N-Dimethyltryptamine (DMT)

N,N-Dimethyltryptamine, more commonly known as DMT or dimethyltryptamine, is a powerful psychedelic and hallucinogen that features an unusually short bioavailability period (the time during which it is active in the bloodstream and causing psychoactivity). DMT is unique in that it is produced by multiple plants and even humans and animals.

DMT was first synthesized in 1931 by Canadian chemist Richard H. F. Manske, although its psychoactive effects were not uncovered until 1956 by Hungarian chemist and psychiatrist Stephen Szára.[2] Szára, through work with human volunteers, identified DMT as an ingredient in snuffs employed during some South American spiritual and religious ceremonies.

DMT features a lengthy, more than millenium-long, history of use in religious rituals in various cultures in South America and the Amazon region, including its incorporation into indigenous Amazonian shamanic practices. Because of the common theme of out-of-body experiences and alien encounters, some users have ascribed mystical or supernatural status to this highly psychotropic chemical.

Characteristics & Distinctions

DMT is characterized by rapid bioavailability onset and intense psychoactivity, traits also offered by several other psychedelic drugs. Two characteristics, however, differentiate DMT from other psychedelics: 1) the fact that it is produced by multiple plants and animals (including humans) and 2) a relatively short duration of action.

During the 1960s, when DMT gained widespread attention among members of the counterculture in North America, it was nicknamed "the businessman's trip" and "the businessman's lunch" drug in the United States due to the fact that a consumer could experience a robust and intense psychedelic experience in less than the time required to take a business day lunch (typically 15-30 minutes)—considerably less time than associated with psychedelics such as LSD or psilocybin mushrooms. Some DMT trips feature a duration of as long as an hour.

DMT can result in intense and otherworldly trips in which common themes are reported by users. These themes include communication with alien beings, exploration of mystical realms, life after death, and out-of-body experiences. Experienced users of psychedelic drugs describe the psychoactivity of DMT trips as being fundamentally different than that of other psychedelic drugs. DMT has been described as taking users to different worlds, whereas more conventional psychedelic drugs modify (either mildly or significantly) the existing world.

Consumption avenues for DMT include inhalation, ingestion (eating), or injection, with the exact efficacy dependent to a large extent upon dosing. Inhalation and injection involve a relatively short duration of only 15 minutes (and sometimes even less).

2 Szára turned his research efforts to DMT following the prohibition of his previous research focus, LSD, and the resulting lack of availability of the drug for further research.

Oral ingestion, however, involves a considerably longer duration of three or more hours if DMT is consumed with an MAOI, as is the case with the traditional ayahuasca teas of a variety of native Amazonian tribes (see Ayahuasca above).

This drug has demonstrated a biphasic response curve in terms of psychoactivity and onset of hallucinations. Lower doses can result in pronounced emotional responses (including euphoria), but a lack of hallucination and severe psychoactivity. At more potent doses, DMT can result in an "intensely colored, rapidly moving display of visual images—formed, abstract, or both."[3]

Legal Status

DMT is Schedule I according to both the United Nations and the United States and is a Class A drug in the United Kingdom and is Schedule III in Canada.

Decriminalization

DMT, when naturally occuring, is decriminalized in Oakland CA and Santa Cruz CA.

Approvals

No relevant approvals for DMT

Studies and Trials

Total Studies	1
Total Active Studies	0
Total Complete Studies	0

Breakdown of Active Studies (Active, Recruiting, Pre-Recruiting)

Study Phase	Number of Studies	Prominent Conditions Studied
Phase I	0	n/a
Phase II	1	Healthy Subjects

Notable Studies

University Hospital Basel is in early phase I of a clinical trial investigating the effect of DMT in healthy subjects.

3 According to the 1990s research of psychiatry professor Dr. Rick Strassman

Ibogaine

Ibogaine is a psychoactive alkaloid that delivers dissociative effects that is derived from the tabernanthe iboga plant, a shrub found in the rainforest of western Africa. It was first discovered in 1901 by French researchers Dybowski and Landrin, who extracted it from the iboga root, although its molecular structure was not determined until 1957.

During the 1940s, ibogaine was researched in France for its neuropharmaceutical potential. In the 1960s, the potential role of this powerful psychedelic drug in the field of psychotherapy was investigated in Chile. The psychoactive properties of ibogaine were first discovered by Pygmy tribes in Central Africa.

Characteristics & Distinctions

Ibogaine has demonstrated promise as a therapeutic agent in assisting those suffering from dependence and addiction to alcohol and hard drugs. It is a compound that adjusts brain chemistry in such a manner that some patients suffering drug dependence who otherwise might experience intense withdrawal symptoms for one or two weeks suffer no withdrawal or cravings when being treated with ibogaine. Researchers are exploring the efficacy of ibogaine with or without the psychedelic response, as well as developing synthetic variations of the drug.

According to drug researcher Emily J. Richer, "During the introspection phase, ibogaine promotes a psychotherapeutic effect that empowers the [patient] to conquer fear and negative emotions that may drive their addictions."[4]

Like other natural and synthetic drugs, ibogaine displays a biphasic response curve in terms of its efficacy. In small doses, this compound is a mild stimulant. In more potent doses, however, it induces a significant psychedelic state.

Researchers of this drug stress the need for proper clinical management of its administration. In the 18-year period between 1990 and 2008, 19 fatalities resulted from the ingestion of ibogaine, six of which resulted from acute heart failure or cardiopulmonary arrest.

An ibogaine experience, or trip, takes place in two phases: 1) the visionary phase and 2) the introspection phase. The visionary phase is a dreamlike stage that features a duration of four to six hours. It is followed by the introspection phase, the trip segment that is responsible for the psychotherapeutic efficacy of the drug and that, it is believed, may give patients the courage and resilience to combat the cravings of alcohol or drug withdrawal.

4 Emily J. Richer MPH, in Complementary and Alternative Therapies and the Aging Population, 2009

Legal Status

In the United States, ibogaine is in the most restricted drug category, Schedule I. Under the United Nations drug scheduling scheme, however, ibogaine is not scheduled (uncontrolled). In Canada it is controlled, having been added to the Prescription Drug List in 2017, while in the United Kingdom it is illegal as part of the Psychoactive Substances Act of 2016.

Decriminalization

Ibogaine is decriminalized in Oakland, CA and Santa Cruz, CA.

Approvals

No relevant approvals for ibogaine.

Studies and Trials

Total Studies	2
Total Active Studies	0
Total Complete Studies	0

Breakdown of Active Studies (Active, Recruiting, Pre-Recruiting)

Study Phase	Number of Studies	Prominent Conditions Studied
Phase I	0	n/a
Phase II	2	Drug Dependence, Alcoholism

Notable Studies

There are two Phase II clinical trials involving human participants, including for methadone detoxification by the International Center for Ethnobotanical Education, Research, and Service in Barcelona, Spain and for the treatment of alcoholism by the University of Sao Paulo in Brazil.

MindMed Inc. has commenced a human safety study of 18-MC, a proprietary compound based on ibogaine.

Ketamine

Ketamine, also known by the street names “special K” and “vitamin K,” was first synthesized in 1962. Today, it is most commonly employed as an anesthetic, and regularly used to treat mental health conditions including anxiety, depression, and suicidal ideation, along with other conditions such as the treatment of asthma, seizure reduction and for pain management.

Clinics which specialize in the administration of ketamine have been growing in popularity. Often these clinics target a single condition such as pain or a patient group such as veterans. Some clinics offer ketamine treatment in conjunction with talk therapy, a similar approach to what is being trialled for MDMA and LSD.

Characteristics & Distinctions

Ketamine is unique among all psychedelic drugs, synthetic or natural, as one of the few to be widely available, but strictly regulated, for the treatment of a wide variety of conditions. Officially, ketamine has only been approved by the FDA for anesthesia and procedural sedation, however clinicians have used it ‘off-label,’ a widely accepted practice, for the treatment, pain management, depression, and suicidal ideation. Many other indications are being studied, and treated off label as well.

Ketamine is typically administered intravenously (IV) or intramuscularly (IM), with the onset times of seconds to 4 minutes and action duration of 15-30 minutes.[5] Other methods of administration include oral, nasal, and subcutaneous. At low doses ketamine leads to sedation and analgesia, while above a certain threshold it induces a dissociative effect.

Legal Status

In the United States, ketamine is a Schedule III drug, while the U.K. categorizes it as Class B, meaning physicians can prescribe and administer the drug for approved and off-label conditions.

Approvals

Ketamine is approved by the FDA for anesthesia and procedural sedation. Esketamine, a derivative, is approved for treatment resistant depression, it is currently being marketed under the brand name Spravato by Johnson & Johnson.

5 Rosenbaum SB, Gupta V, Palacios JL. Ketamine. [Updated 2020 Mar 31]. In: StatPearls [Internet].

Studies and Trials

Total Studies	925
	34
Total Complete Studies	444

Breakdown of Active Studies (Active, Recruiting, Pre-Recruiting)

Study Phase	Number of Studies	Prominent Conditions Studied
Phase I	42	Depression, Mental Health Disorders, Pain, Healthy Patients
Phase II	54	Depression, Mental Health Disorders, Pain and Pain Related Conditions
Phase III	52	Pain, Procedure Related Pain and Sedation, Suicidal Ideation, Depression, Mental Health Disorders
Phase IV	64	Pain, Procedure Related Pain and Sedation, Suicidal Ideation, Depression, Mental Health Disorders

Notable Studies

Ketamine is extensively studied, there are hundreds of studies completed or underway to evaluate its effectiveness to treat mental health, pain and other conditions.

Lysergic Acid Diethylamide (LSD)

Lysergic acid diethylamide, more commonly called LSD and featuring the street names "acid" and "blotter" (among many others) is arguably the most popular psychedelic drug of the past fifty years. LSD has served as a mainstay and right of passage for teens, college students, and participants in a variety of subcultures. It is estimated that roughly 10% of Americans have tried LSD at least once in their life.

LSD was first derived from ergot, a fungus that develops on grains such as rye. First synthesized in the late 1930s, the powerful and mind altering psychedelic effects of this drug went unknown until several years later when a research chemist in Switzerland, Albert Hoffman, accidentally absorbed the potent drug through his skin during the course of his laboratory work.

The unusual and pronounced effects of the drug so enticed the researcher's curiosity that he elected to self-experiment three days later. This first LSD trip, which has become immortalized within psychedelic culture as Bicycle Day, occurred, in large part, during Hoffman's bicycle commute home from work on April 19, 1943.

During the 1950s and 1960s, LSD was sold as a pharmaceutical drug under the name Delysid.

Characteristics & Distinctions

LSD trips are typically characterized by mental and visual hallucinations. Bioavailability onset is 30-60 minutes, with a duration of up to 12 hours. LSD is ingested orally via capsule or tablet, a moderate dosage is produced at 1 to 3 micrograms/kg body weight.[6]

Medicinal efficacies of LSD currently or in the past under investigation include treatment of anxiety, depression, drug and alcohol dependence, cluster headaches, Alzheimer's disease, Tourette's syndrome, and Attention Deficit Hyperactivity Disorder (ADHD).

Potential negative side effects that occur in some users of this drug include anxiety, delusions, and paranoia.

Legal Status

LSD is classified as a Schedule I drug by both the United States and the United Nations. In the United Kingdom, it is considered a Class A drug, while it is Schedule III in Canada.

6 Hwang KAJ, Saadabadi A. Lysergic Acid Diethylamide (LSD) [Updated 2020 Apr 21]. In: StatPearls [Internet]

Studies and Trials

Total Studies	12
Total Active Studies	0
Total Complete Studies	6

Breakdown of Active Studies (Active, Recruiting, Pre-Recruiting)

Study Phase	Number of Studies	Prominent Conditions Studied
Phase I	3	Healthy Patients
Phase II	3	Cluster Headaches, Depression, Anxiety
Phase III	0	N/A
Phase IV	0	Chronic Pain

Notable Studies

MAPS completed a Phase II trial with LSD in conjunction with psychotherapy for the treatment of anxiety in patients with life threatening illnesses. The study was conducted by Dr. Peter Gasser in Solothurn, Switzerland.

MindMed Inc, is conducting a Phase II trial with LSD for treatment of anxiety at the University Hospital Basel.

Methylenedioxymethamphetamine (MDMA)

Methylenedioxymethamphetamine, or MDMA, is a popular psychedelic drug that is commonly used within party and rave subcultures. Also known by the street names "ecstasy," "molly," and "the hug drug," this particular synthetic chemical imparts feelings of sometimes intense empathy and joy combined with increased energy levels.

Anton Kollisch, a scientist at the German pharmaceutical company Merck, first synthesized MDMA in 1912 when attempting to develop a vasoconstrictor drug. After gaining massive popularity on the underground, the U.S. Drug Enforcement Administration in 1985 declared an emergency ban on MDMA, giving it Schedule I status along with a long list of other psychedelic drugs, including LSD.

In 2016, it was estimated that 21 million people around the world between the ages of 15 and 64 used MDMA as a recreational drug. In the United States, about 7% of the population is believed to have experimented with MDMA.

Characteristics & Distinctions

MDMA features a bioavailability onset of 30 to 45 minutes (when consumed orally) and a duration of three to six hours. It is typically consumed orally in a pressed tablet form or nasally in a powdered format. Studies show doses range from 50mgs to 150mgs. Desired effects include arousal, sensual enhancement, feelings of euphoria, and emotional closeness to others.[7]

Research indicates that MDMA may be helpful for those suffering PTSD to overcome the often debilitating condition. It is theorized that the joy and empathy experienced by MDMA users may be pivotal to their ability to face their fears and directly address the memories fueling their condition and triggering episodes. If traumatic memories can be addressed in the absence of overwhelming fear and paranoia, it is theorized that patients are then able to properly confront and deal with these painful memories, processing them and progressing beyond their disease. This style of treatment is often referred to as psychedelic assisted psychotherapy and involves a treatment protocol over a number of therapy sessions, some while dosed with MDMA, others while not.

Legal Status

MDMA is Schedule I in both the United States and according to the United Nations. In the United Kingdom, it is a Class A drug, while in Canada it is classified as Schedule I.

7 Figurasin R, Maguire NJ. 3,4-Methylenedioxy-Methamphetamine (MDMA, Ecstasy, Molly) Toxicity. [Updated 2020 May 24]. In: StatPearls [Internet]

Approvals

The FDA has granted the Multidisciplinary Association for Psychedelic Studies (MAPS) breakthrough therapy and expanded access designations for their use of MDMA to treat PTSD. A breakthrough therapy is "a drug intended to treat a serious or life threatening disease or condition and early clinical evidence shows substantial improvement over existing therapies."[8] Expanded access is a "potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available."[9]

Studies and Trials

Total Studies	43
Total Active Studies	2
Total Complete Studies	32

Breakdown of Active Studies (Active, Recruiting, Pre-Recruiting)

Study Phase	Number of Studies	Prominent Conditions Studied
Phase I	9	Healthy Patients, PTSD, Autism, Alcohol Use Disorder
Phase II	2	PTSD
Phase III	2	PTSD
Phase IV	0	N/A

Notable Studies

MAPS is currently involved in two (one active, one not yet recruiting) Phase III trials across multiple sites around the world to study MDMA assisted psychotherapy for the treatment of PTSD.

8 https://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fact-sheet-breakthrough-therapies

9 https://www.fda.gov/news-events/public-health-focus/expanded-access

Psilocybin

Psilocybin is a naturally occurring psychedelic chemical that is produced by more than 100 species of mushrooms.[10] It produces psychotropic effects, hallucinations and extreme perceptual distortions. Although occurring in many mushrooms, psilocybin is most commonly harvested from the species Psilocybe cubensis.

Prehistoric murals and rock paintings uncovered in Spain and Algeria indicate that human use of psilocybin mushrooms may predate recorded history. But, psilocybin mushrooms were popularized in western culture following the 1957 publication of an article in LIFE Magazine featuring American mushroom enthusiast R. Gordon Wasson. Wasson, who discovered a Mexican tribe that used psilocybin mushrooms, collected a sample and provided it to Swiss chemist Albert Hoffman, the scientist responsible for the synthesis of LSD. Hoffman was able to isolate and synthesize the compound and began producing 2 mg capsules that he distributed to other researchers.

Characteristics & Distinctions

Some users of psilocybin mushrooms report spiritual experiences, with the contortion of a user's perception of time being a common effect. This common effect of psilocybin is sometimes called "time stretch" and, in extreme cases, can result in only minutes being perceived as hours. Some users report extreme perceptions such as "time stood still."

Psilocybin mushrooms are ingested orally, onset time ranges from 30 minutes to 2 hours and can last between 4 and 12 hours.[11] Once inside the human body, psilocybin is metabolized to psilocin. It is psilocin, more precisely, that produces the psychedelic and hallucinogenic effects, a result of interactions with receptors in the brain.

Psilocybin can produce some negative side effects, including disorientation, confusion, panic attacks, and nausea.

Legal Status

Psilocybin is classified as a Schedule I drug according to both the United Nations and the United States. In the United Kingdom, it is considered a Class A drug, while it is Schedule III in Canada.

Decriminalization

Psilocybin is decriminalized in Denver, CO, Oakland, CA and Santa Cruz, CA. At the time this Report went to publication campaigns were underway in jurisdiction across the United States,to legalize or decriminalize psilocybin and other naturally occurring psychedelics.

10 Clinical potential of psilocybin as a treatment for mental health conditions, Jeremy Daniel, PharmD, BCPS, BCPP corresponding author1 and Margaret Haberman, PharmD, BCPP2

11 Tran HH, Juergens AL. Mushroom Toxicity. [Updated 2020 Mar 24]. In: StatPearls [Internet].

Approvals

The FDA has granted COMPASS a breakthrough therapy designation for their use of psilocybin for their treatment of treatment resistant depression, and to Usona Institute for their use with major depressive disorder.

Studies and Trials

Total Studies	40
Total Active Studies	7
Total Complete Studies	9

Breakdown of Active Studies (Active, Recruiting, Pre-Recruiting)

Study Phase	Number of Studies	Prominent Conditions Studied
Phase I	18	Depression, OCD, Anorexia, Migraines and Cluster Headaches
Phase II	10	Depression, Substance Abuse, Migraines and Cluster Headaches
Phase III	0	N/A
Phase IV	0	N/A

Notable Studies

Usona Institute, Johns Hopkins, Imperial College and Compass Pathways are all engaged in Phase II trials with psilocybin for either Major Depressive Disorder or Treatment Resistant Depression.

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