

# PSYCHEDELICS AND CANADA'S REGULATORY LANDSCAPE

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The capital markets landscape in Canada has recently seen an increase in investments related to psychedelics. Companies operating in this industry area have been listed on Canadian stock exchanges, and others are raising capital and growing in the exempt market space, with future plans to go public. Herein, we outline the Canadian regulatory landscape for operation of a psychedelics company.

This emerging industry is experiencing players that wish to capitalize on historical medical and psychiatric research combined with the more open climate in today's world that challenges old norms of how to treat issues like mental illness and drug addiction. Due in part to the increased focus on the importance of mental wellness and the legalization of cannabis in Canada, psychedelics are starting to be viewed as a potential avenue for treatment. Though psychedelics and cannabis share a historical designation as being controlled substances under the federal *Controlled Drugs and Substances Act* ("**CDSA**"), this is not sufficient to relate the two industries to each other in every way. Whereas the recreational market for cannabis created a significant amount of consumer demand, companies that operate in the psychedelics industry are not vying to create and sell recreational substances.

While the industry is not monolithic, companies in the psychedelic space are often focused on clinics and treatment centres, investment into processes for extraction, pharmaceutical applications, or other endeavours to utilize the therapeutic benefits of these substances. For companies focused on pharmaceuticals, this means the path to success will often be predicated on discoveries as well as the completion of highly regulated and staged testing processes required for government approval before the drugs can go to market. Depending on the jurisdiction of operation, non-pharmaceutical companies may also be subject to varying degrees of regulation.

## Primer on Psychedelics

Psychedelics are drugs with perception-altering or mind-expanding effects. Most people consider them a recreational drug but in fact, they have a long history of being used medicinally. Naturally occurring psychedelics such as magic mushrooms (psilocybin and psilocin), the San Pedro and peyote cactus (mescaline), and ayahuasca (DMT) have been used as medicine in traditional ceremonies for centuries to treat a wide array of maladies and stimulate spiritual growth.<sup>[1]</sup> Many of the conditions treated with these

psychedelics we would likely view as mental conditions today, such as addiction, depression, or post-traumatic stress disorder.

The genesis of LSD, MDMA, and ketamine were drugs with great potential to treat mental illnesses and be used as a psychiatric tool due to their perception altering and mood-regulating qualities. Although initial clinical studies showed promise, they were all shelved before any conclusive results were yielded due to the negative shift in the public and political perception of psychedelics following the counter-culture movement of the 1960s.<sup>[2]</sup> Psychedelics were being used recreationally at the time and an almost worldwide ban on psychedelics came into effect to put an end to it. Unfortunately, this also served to limit medical research due to the increased regulatory burden, and associated cost, of working with these compounds.

Today, as society becomes better informed on mental health and grows its awareness of how to treat mental illnesses, interest in psychedelics has been greatly renewed for their immense treatment potential. The laws prohibiting their use, and the rationale used to set up those prohibitions are being challenged. As a result, the public is opening up to the idea of psychedelics as not only a treatment tool, but potentially the most effective treatment tool for some conditions.<sup>[3]</sup> More and more studies are being released showing that psychedelics are actually some of the least harmful drugs, ranked well below alcohol, tobacco, and even cannabis.<sup>[4]</sup> It is a new era as governments are taking notice and psychedelic research centres are opening, universities are conducting studies, and clinical trials are getting approved. Effectively, society is abuzz with discussion about the potential benefits of these drugs.

### **Treatment under Canadian Law**

Psychedelic drugs are “controlled substances” under the *CDSA*. Controlled substances are categorized into schedules based upon their perceived danger.<sup>[5]</sup> Schedule 1 substances are deemed to have the highest potential for abuse and carry the most severe penalties for violations – the severity of the penalties decreases for Schedule 2 substances and so on.

Most psychedelics are Schedule 3 substances, including LSD, psilocybin and psilocin (magic mushrooms), mescaline (peyote and San Pedro cactus), and DMT (found in many plants, but most commonly an ingredient in ayahuasca). MDMA and ketamine are both Schedule 1 substances.

The *CDSA* generally prohibits all uses of controlled substances unless an exemption is granted under section 56 of the *CDSA* or the regulations allow otherwise.<sup>[6]</sup> For this reason, use of the section 56 exemption, as outlined below, or increased approvals under the existing regulatory process, appear to be the most likely sources of expansion of participants becoming more active in the industry.

#### *Section 56 Exemption*

The Minister of Health can grant exemptions under section 56 of the *CDSA* to use controlled substances if it is deemed to be necessary for a medical or scientific purpose or is otherwise in the public interest.<sup>[7]</sup> It is not clear exactly how and when this exemption may be granted for psychedelics. In 2017, a group of doctors in British Columbia submitted an application for a section 56 exemption to have access to psilocybin to treat patients experiencing terminal distress. That application was denied in March of 2020 on the basis that there is insufficient evidence to demonstrate the medical need for psilocybin.<sup>[8]</sup> But given the public and scientific interest in mental health treatments using psychedelics it stands to reason that section 56 exemptions could be an avenue for getting access to controlled substances like psychedelics in the future once further studies have been published.

### *Regulation Exemptions*

Despite the general prohibition on controlled substances, there are regulations that can allow authorized persons to possess, produce, sell, import/export, and transport controlled substances. The *Food and Drug Regulations* gives authorization to persons (including licensed dealers and those exempted under section 56 of the *CDSA*) to have access to psychedelics.<sup>[9]</sup> Ketamine is regulated as a “narcotic” under the *Narcotic Control Regulations* and is the only psychedelic governed by this regulation. It is already legally available for medical use.<sup>[10]</sup>

These regulations provide a framework for expanding and monitoring the legal use of controlled substances in Canada as well as, importantly, issuing licences to prospective dealers.

### *Licensing*

Any person who ordinarily resides in Canada or a corporation, which has a head office in Canada, is eligible to apply for a dealer’s licence for controlled substances. Currently, a licensed dealer may only sell psychedelics to an institution for clinical or research purposes. Prior to the sale, the research institution must obtain authorization from Health Canada.<sup>[11]</sup> A licensed dealer also has the ability to import and export controlled substances, however, a permit from Health Canada must be obtained for each import or export.<sup>[12]</sup> In short, while a dealer’s licence opens the door for buying and selling psychedelics, the activities are still heavily regulated.

An overview of the policy for licensed dealer applications can be found in the Government of Canada’s [Application Guide](#).

### *Precursors, Spores, and Plants*

Precursors are chemicals that may be used to make controlled substances like MDMA, LSD, and ketamine. The *CDSA* prohibits activities associated with most precursors used to make controlled substances barring a

section 56 or regulatory exemption.<sup>[13]</sup>

While no law allows it, the sale of magic mushroom spores and grow kits has been tolerated in Canada for some time. The argument for legality of spores is premised on the fact that the spores do not contain a controlled substance – there is no psilocybin in the spores themselves. Following this approach to the law, it would hold that once the spores germinate and a magic mushroom’s mycelium forms, it becomes a controlled substance as that is when psilocybin is present.

The peyote cactus is specifically exempt from the Schedule 3 controlled substances list under the *CDSA*, despite it containing mescaline, and is legal to grow, sell, and consume in Canada. But extracting and isolating the mescaline from the peyote plant would violate the *CDSA* as one would then be in possession of a controlled substance: mescaline. This exemption for peyote (and not mushrooms or other plants) is because of the historical significance of peyote with Canada’s Indigenous communities.

The San Pedro cactus is not exempt and is only permitted to grow for ornamental purposes. The same goes for the many plants that contain DMT – extracting the controlled substance would violate the *CDSA*.

## Conclusion

The legal and regulatory landscape concerning psychedelics continues to evolve as it becomes more traversed. We foresee the potential for changes through an increase in the number of actors on the basis of broader applications of section 56 of the *CDSA* or increasing approvals granted by Health Canada under existing regulations. Notwithstanding that, it is important to note that as of today, the psychedelics industry in Canada is highly regulated, and companies seeking to operate within it will need to contend with complexities around compliance. Though the investing public has clearly demonstrated comfort with supporting it by capitalizing issuers operating within this industry, psychedelics remains at an emerging stage.

We will continue to monitor developments in the psychedelics industry, and update on changes in the legal and regulatory landscape in due course.

by Leila Rafi, Sasa Jarvis and David Jol (Student-at-Law)

[1] David E. Nichols, “Psychedelics” (2016), *Pharmacological Reviews* 2016 Apr; 68(2): 264–355, online: [ASPET: Pharmacological Reviews](#).<sup>[ps2id id='1' target='']</sup>

[2] *Ibid.*<sup>[ps2id id='2' target='']</sup>

[3] Ira Byock, “Taking Psychedelics Seriously” (2018), *Journal of Palliative Medicine*, 2018 Apr 1; 21(4): 417–421, online: [Mary Ann Liebert, Inc., publishers](#).<sup>[ps2id id='3' target='']</sup>

[4] David J. Nutt, Leslie A King, and Lawrence D Phillips, “Drug harms in the UK: a multicriteria decision analysis” (November 1, 2010), [The Lancet](#), Volume 376, Issue 9752, P. 1558-1565, online: [The Lancet](#).<sup>[ps2id id='4'</sup>

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[5] Government of Canada, “Controlled Substances and Precursor Chemicals” (27 April 2020), online: [here](#). [ps2id id='5' target=""]

[6] *Controlled Drug and Substance Act*, SC 1996, c 19, s 4-7. [ps2id id='6' target=""]

[7] Government of Canada, “Controlled Substances and Precursor Chemical Exemptions” (20 August 2015), online: [here](#). [ps2id id='7' target=""]

[8] Jackie Dunham, Avis Favaro, and Elizabeth St. Philip, “Terminally ill Canadians apply for legal access to 'magic mushrooms' drug” (8 June 2020), online: [CTV News](#). [ps2id id='8' target=""]

[9] *Food and Drug Regulations*, CRC, c 870, s J (1978) [*FDR*]. [ps2id id='9' target=""]

[10] Government of Canada, “Ketamine” (3 April 2020), online: [here](#). See also *Narcotic Control Regulations*, CRC, c 1041, s 3(1) (1978). [ps2id id='10' target=""]

[11] Government of Canada, “Frequently Asked Questions – Food and Drug Regulations” (27 June 2016), online: [here](#). [ps2id id='11' target=""]

[12] *FDR*, *supra* note 9 at s J.01.038 and J.01.048. [ps2id id='12' target=""]

[13] Government of Canada, “Regulated Controlled Substances and Precursors” (31 January 2019), online: [here](#). [ps2id id='13' target=""]

### **A Cautionary Note**

The foregoing provides only an overview and does not constitute legal advice. Readers are cautioned against making any decisions based on this material alone. Rather, specific legal advice should be obtained.

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