

THE CANADIAN CAPITAL MARKET IS PSYCHED: AN UPDATE ON THE GROWING WAVE IN THE PSYCHEDELICS INDUSTRY

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Introduction

Psychedelics have experienced a positive revival in recent years, having emerged as a potential tool for treating certain mental health illnesses, pain disorders, and neurological disorders. Research has highlighted potential benefits of psychedelics.^[1] Unsurprisingly therefore, companies have been entering the space at a dizzying pace, seizing the market opportunity to raise money from eager investors and go public. The Canadian Securities Exchange (the “**CSE**”) has been busy, hosting the majority of the new listings.

Regulatory Overview

Psychedelics are classified as “controlled substances” under the *Controlled Drugs and Substances Act* (“**CDSA**”). Under the CDSA, controlled substances are separated into schedules based on a number of factors, with Schedule I representing the substances that have been determined by the federal government to carry the highest potential for abuse. Most psychedelics are characterized as Schedule III substances (for example, LSD, psilocybin, psilocin, mescaline and DMT), with the exception of Ketamine and MDMA, which are Schedule I substances. Although the CDSA prohibits the possession and use of controlled substances including psychedelics, exemptions may be granted by the Minister of Health (the “**Minister**”) for a medical or scientific purpose or where it would otherwise be in the public interest under Section 56 of the CDSA (“**Section 56 Exemption**”), or for clinical or research purposes under the *Food and Drug Regulations* (the “**Regulations**”)^[2] and *Narcotic Control Regulations*.^[3]

For additional background information on the psychedelic space and the relevant regulatory regime under the CDSA, please see our previous bulletin: [Psychedelics and Canada’s Regulatory Landscape](#).

Psychedelics in Capital Markets

Since the beginning of 2020, over 20 psychedelics companies have listed on the CSE, TSX Venture Exchange (“**TSX-V**”) and the NEO Exchange (“**NEO**”). Over two-thirds of these newly-listed companies became publically traded by way of a reverse-takeover. In addition to these new listings, several other public companies have

entered the psychedelics space by acquiring existing psychedelics companies or by expanding their respective businesses to include psychedelics.

The majority of these public companies focus on the research, development and commercialization of psychedelics for medical purposes. Although less common, some of these newly-listed companies operate therapeutic clinics, offering psychedelic-assisted therapy to treat an array of mental illnesses. At least three of these companies also produce and sell “functional mushroom” products such as mushroom-infused coffee, tea, skin creams, and similar consumer products. Functional mushrooms are fundamentally different from psychedelics – specifically, they do not contain psilocybin or other ingredients classified as controlled substances in Canada or the United States. They are often marketed for use in helping with stress, inflammation, weight loss, and similar goals, rather than for the treatment of physical and mental health disorders. It is helpful to understand the distinction.

Of the psychedelics companies to ride the wave and go public in Canada since the start of 2020, at least two have obtained Section 56 Exemptions for the use of psilocybin for scientific purposes. At least three others have either applied for or announced plans to apply for a Section 56 Exemption. Notably, some companies that are listed on a Canadian stock exchange do not operate in Canada so may not have a need for a Section 56 Exemption.

Regulatory Update

Special Access Program

A recent proposal by Health Canada to amend the Regulations with respect to the Special Access Program (“**SAP**”) may open another route through which patients may access drugs, including psychedelics, which are otherwise unavailable in Canada. Under the SAP, pursuant to the Regulations, the Minister may issue a letter authorizing the sale of otherwise unavailable drugs to a Practitioner who has submitted a request for same. “Practitioner” is defined under the Regulations as a person that is entitled to treat patients with prescription drugs and is practicing in their province.^[4] Typically, this would include medical doctors among others.

The proposed amendments would repeal certain provisions of the SAP that currently prevent access to psychedelics under the program.^[5] In 2013, the federal government made changes to the Regulations that prohibited the Minister from issuing authorization letters under the SAP for “restricted drugs,” which include LSD, psilocin and psilocybin, among other psychedelics.^[6] Accordingly, the only method for a patient to access such “restricted drugs” was through a Section 56 Exemption. Health Canada’s proposed changes, however, include removing the prohibition on “restricted drugs.” If the proposal is successful, Practitioners in Canada would have an additional avenue through which they could obtain psilocybin or psilocin on behalf of patients with serious or life-threatening conditions, without the need for an available clinical trial.

Section 56 Exemptions

On August 4, 2020, Patty Hajdu, the Minister of Health, granted the first publicly known legal exemptions for psilocybin for medical use^[7] to four terminally ill cancer patients, allowing them to receive psilocybin therapy as part of their end-of-life care.^[8] Following the grant of this initial exemption, the Minister has granted a slew of other exemptions for both clinical and research purposes, greatly expanding the use of psilocybin in Canada. Accordingly therefore, a substantial expansion of authorized activity in the space has taken place.

The four exemptions granted in August 2020 were clinical exemptions, and have been followed by more than 20 additional clinical exemptions.^[9] Notably, while most of the clinical exemptions granted by the Minister are for palliative care, at least one exemption was granted to a former cancer patient, marking the first non-palliative exemption granted under the CDSA.^[10] Therefore, while the clinical use of psilocybin remains primarily limited to palliative care patients, the scope of use is gradually expanding. Furthermore, a number of healthcare practitioners – including psychologists, psychiatrists, clinical counselors, social workers, general practitioners and nurses – were granted exemptions to take part in a ten-week psilocybin therapy training program run by B.C.-based, non-profit TheraPsil.^[11] Through this program, the participating healthcare workers will focus on how to facilitate legal, psilocybin-assisted therapies, in part by undergoing their own guided psilocybin experience in order to better understand the process their own patients will go through. In connection with the Section 56 Exemptions described, psychedelic industry companies have sought to expand their ability to produce psilocybin and other psychedelics for clinical and research purposes through Health Canada's licensing regime.^[12]

Research is very important to the growing acceptance of the use of psychedelics for a variety of medical purposes. In addition to clinical exemptions, Health Canada has granted a number of exemptions to institutions to conduct research on psilocybin mushrooms. Multiple companies in Canada have recently made announcements related to Section 56 Exemptions they have received from Health Canada to conduct pre-clinical research. Notably, some of these companies have recently announced advances achieved through such research.

What Lies Ahead

Although there has been an increase in the number of both psychedelics companies in the Canadian capital markets and Section 56 Exemptions granted by Health Canada, the psychedelics industry in Canada remains highly regulated against the backdrop of a capital markets regime that is complex. Companies seeking to operate within the industry, raise funds and potentially have their stock listed on a Canadian exchange will need to contend with compliance obligations. Accordingly, having legal counsel that has experience in the industry to help navigate regulatory complexities is highly recommended. While the positive renaissance that

the psychedelics industry is currently experiencing appears to have made the investing public more comfortable supporting its participants' financing efforts, especially compared to how psychedelics were viewed in the past, applications for the use of psychedelics that these companies are currently exploring – whether to treat anxiety, post-traumatic stress disorder, addiction, traumatic brain injury, epilepsy or any other physical or mental disorders – are in their early stages and will likely be subject to further significant developments as more research and testing for efficacy and safety is conducted. We will continue to monitor developments in the psychedelics industry and provide updates on the evolving legal and regulatory landscape.

[1] Ira Byock, “Taking Psychedelics Seriously” (2018), *Journal of Palliative Medicine*, 2018 Apr 1; 21(4): 417–421, online: Mary Ann Liebert, Inc., publishers.

[2] CRC, c 870 [FDR].

[3] CRC, c 1041.

[4] FDR, supra note 2, Pt. C, Div. 1, C.01.001.

[5] [Canada Gazette, Part I, Volume 154](#)

[6] *Ibid*, C.08.010(3).

[7] The first exemption granted with respect to psychedelics generally was in 2017, when two churches in Montreal obtained exemptions to use ayahuasca in connection with a religious rite.

[8] Alexandra Mae Jones, “[Four terminally ill Canadians get special exemption to use psychedelic therapy](#)” (4 Aug 2020) CTV News.

[9] Camille Bains, “[Patient hopes Canada will introduce regulations for psychotherapy with ‘magic mushrooms’](#)” (18 Jan 2021), CBC.

[10] Cindy E. Harnett, “[Former cancer patient finds deep healing in psilocybin trip](#)” (13 December 2020), *Times Colonist*.

[11] TheraPsil, “[17 Canadian Healthcare Professionals Approved to Use Psilocybin for Professional Training](#)” (8 December 2020) [Press release].

[12] Karl Yu, “[Lab expansion project in Nanaimo to aid magic mushroom, psychedelics research](#)” (21 March 2021), BC Local News.

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A Cautionary Note

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