

2022 STARTS ON A HIGH – UPDATES IN THE PSYCHEDELICS INDUSTRY AND A LOOK BACK AT 2021

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After significant growth last year, the psychedelics industry began 2022 with news of the reinstatement of Health Canada’s highly anticipated amendments to the Special Access Program (“SAP”). These changes now permit physicians to request access to psychedelics for eligible patients. This comes after developments in the past year both in terms of public opinion shifting in support of psychedelics and the navigation of Canada’s existing regulatory regime to allow access to psychedelics in limited circumstances through an exemption granted by the Minister of Health. Each of these developments is discussed in turn below.

Physicians in Canada May Now Request Access to Psychedelics for Patients

On January 5, 2022, Health Canada made effective amendments (the “Amendments”) to the SAP. Following the Amendments, medical practitioners may request access to certain psychedelics for eligible patients. In 2013, prior amendments to the *Food and Drug Regulations* (“FDR”)^[1] resulted in the disallowance of restricted drugs from request under the SAP, which eliminated the ability for patients to access drugs such as psilocybin for medical treatment outside clinical trials or an exemption under section 56 of the *Controlled Drugs and Substances Act* (“CDSA”),^[2] discussed further below.

Under the SAP, the Minister of Health may issue a letter of authorization, whereby a manufacturer of an unapproved drug may provide that drug to a medical practitioner, for the treatment of a patient with a serious or life threatening condition. After the Amendments, a letter of authorization may now be given for psychedelics. The treatment is accessible on a case by case basis, and is intended for emergency situations where “conventional treatments have failed, are unsuitable or unavailable”.^[3]

Health Canada noted in a statement accompanying the Amendments that typically, restricted drugs are not considered drugs with approved medical uses, however the efficacy and safety of certain restricted drugs for treatment of mental and physical maladies has become more established in the present day than in 2013.^[4] These scientific developments and advancements are accompanied by a shift in public perception of psychedelics, which Health Canada flagged in its discussion of letters received during a consultation period following the notice of its intention to restore access to psychedelics through the SAP in December 2020.

Notably, there was less than a 2% rate of opposition to the Amendments, as gleaned from the hundreds of submissions provided during this consultation period.^[5]

This level of support discovered by Health Canada appears to be consistent with other reported figures. In August 2021 the Canadian Psychedelic Association revealed survey findings from Nanos Research which demonstrated that 82% of Canadians approve the use of psilocybin-assisted therapy for people suffering from an end-of-life illness, and 78% would support a government that legalized the same.^[6] With increased public support, voters and legislators alike have begun to reflect that support in their decision-making, including through legislative efforts in the United States seeking to decriminalize certain psychedelics at state and local levels of government.^[7]

Regulatory Regime and Section 56

As provided in our [earlier update](#) in May 2021, psychedelics are classified as “controlled substances” under the CDSA. Controlled substances are categorized in schedules under the CDSA, with Schedule I drugs being viewed as having the highest potential for abuse, and thereby, carrying the most severe penalties. Most psychedelics, including psilocybin, psilocin, mescaline, and DMT, are characterized as Schedule III drugs, while only ketamine and MDMA are classified as Schedule I substances.

Generally, the CDSA prohibits the possession, sale, import, export, production, transfer and transport of all controlled substances. However, the Minister of Health may grant an exemption under section 56 of the CDSA (“s.56 Exemption”) if he or she is of the opinion that the exemption is necessary for a medical or scientific purpose, or otherwise in the public interest. The Minister of Health may also grant an exemption for clinical or research purposes under the FDR and the *Narcotic Control Regulations* (“NCR”).^[8]

Under the FDR, individuals and corporations located in Canada are eligible to apply for a dealer’s licence for psilocin, psilocybin, mescaline, DMT and MDMA. However, a licensed dealer in Canada may only sell psychedelics to an institution for clinical or research purposes, who must obtain authorization from Health Canada for same.^[9] A licensed dealer may also import and export controlled substances, though a permit from Health Canada is required for each import or export.^[10] A dealer’s license is also available under the NCR for ketamine, and generally, the same restrictions noted here apply. Accordingly, though a dealer’s license opens the door for buying and selling psychedelics, a dealer’s activities are heavily regulated.

The regulatory regime and the medical use of psychedelics are the primary reasons that psychedelics should not be compared to cannabis, which has the distinction of having gained acceptance in the adult recreational market. There are also potentially higher costs of entry for businesses wishing to operate in the psychedelics industry area and there is a longer period of testing before commercialization may be able to occur (and commercialization is not guaranteed). For further background on the regulatory landscape governing

psychedelics, please see our previous [bulletin](#) published in July 2020.

Update on s. 56 Exemptions

In August 2020 the Minister of Health granted four individual Canadians a s.56 Exemption each to use psilocybin for cancer treatment.^[11] Once the applications were made on an individual basis as opposed to being made in a group, they were granted. Since this watershed moment, the Minister of Health has granted a total of 66 s.56 Exemptions. The latest figures indicate that at least 47 individuals have now been granted s.56 Exemptions for end-of-life psychological distress, 19 s.56 Exemptions have been given to healthcare practitioners for training purposes and several more to institutions and companies for research.^[12] Moreover, recent reports indicated that Health Canada acknowledged more than 150 applications for s.56 Exemptions remain unanswered^[13] indicating a high volume of applications.

In 2021, government bodies have also applied for s. 56 Exemptions to decriminalize the personal possession of small amounts of controlled substances for public health purposes. In November 2021, British Columbia made a request to Health Canada for a s.56 Exemption to permit individuals over the age of 19 to have personal amounts of illicit hard drugs such as heroin, fentanyl, methamphetamine, and crack and powder cocaine (without penalty). British Columbia will consider a similar exemption request for other substances such as psilocybin and MDMA at a later date.^[14] This comes on the heels of the City of Vancouver requesting a s.56 Exemption in May 2021 which included permitting possession of up to a certain amount of psychedelics, proposed by the City of Vancouver in its submission to Health Canada to be 20 g for psilocybin mushrooms and 3 g for ketamine.^[15] A decision has not yet been published in regards to each of the aforementioned exemption requests.

The City of Toronto is now in the process of seeking a similar exemption of its own. In November 2021, Toronto's Medical Officer of Health prepared a report to action seeking administrative approval to be able to submit a request to Health Canada for a city-wide s.56 Exemption. On December 6, 2021, Toronto's Board of Health unanimously approved the report to action. Currently, the City of Toronto is in the process of submitting a request to Health Canada which would call upon the federal government to develop a national framework to permit the simple possession of all drugs for personal use, along with a Toronto-wide s.56 Exemption, which if granted, would permit people in Toronto to possess small amounts of drugs for personal use.^[16]

Growth in Capital Markets Activity for Psychedelics Issuers

Since the beginning of 2021, another 34 or so psychedelic companies have listed their securities on the CSE, TSX Venture Exchange, or the NEO Exchange in Canada and we expect further growth in the future. Viewing listings in a larger period, since the beginning of 2020, at least 50 psychedelic companies have listed their securities, and the CSE has stated that between January 2021 and November 2021, companies operating in the

psychedelics industry that have listed their securities on the CSE have raised approximately CAD\$289 million.^[17] Another item of note is that the world's first psychedelics exchange-traded fund was listed on the NEO exchange in 2021. Overall, there are currently at least 75 companies focused on the psychedelics industry trading their securities on Canadian exchanges.

2022: A New Year for Psychedelics

Psychedelics have come a long way since the 1970s at which time they faced a negative backlash as a result of the “war on drugs” in the United States, and corresponding restrictions in countries such as Canada. With a growing body of research, shifting demographics and a general openness to evaluate non-conventional ways to deal with existing challenges, the public has become more receptive to psychedelics for medical and therapeutic purposes.

It is anticipated that access to drugs and treatments that incorporate psychedelics may increase through the recent Amendments to the SAP as well as s. 56 Exemptions continuing to be granted by the Minister of Health. However, neither of these routes for access should be viewed as decriminalizing psychedelics. Despite the developments potentially increasing access to psychedelics for certain eligible patients, it is important to note that psychedelics and activities related to it remain heavily regulated. Accordingly, actors within the psychedelics space must remain aware of the legal complexities surrounding the industry.

The team at McMillan is available to assist, and will continue to monitor developments to the industry and regulations as they arise.

[1] *FDR*, CRC, c 870.

[2] *CDSA*, SC 1996, c 19.

[3] Health Canada – “[Regulations Amending Certain Regulations Relating to Restricted Drugs \(Special Access Program\): SOR/2021-271](#)”.

[4] *Ibid.*

[5] *Ibid.*

[6] Global Newswire – [Canadian Psychedelic Association news release](#).

[7] [City of Seattle - Seattle City Counsel Draft Resolution](#); Bloomberg – “[Seattle Votes to Decriminalize Psilocybin and Similar Substances](#)”; Detroit Free Press – “[Detroit decriminalizes psychedelic mushrooms: What it means](#)”; California Legislative Information – [Bill SB519 Information](#); Oregon Secretary of State – [Complete Text of Initiative #34](#).

[8] *NCR*, CRC, c 1041.

[9] Government of Canada – [Frequently Asked Questions – Food and Drug Regulations](#).

[10] *FDR*, *supra* note 1 at J.01.038 and J.01.048.

[11] To watch a CBC televised interview of a panel, including the first Canadian granted a s. 56 Exemption for psilocybin therapy and McMillan partner Leila Rafi, please click [here](#).

[12] CBA National Magazine – [“The New Cannabis?”](#).

[13] CBC – [“B.C. non-profit challenges Health Canada to end 50-year prohibition on magic mushrooms”](#).

[14] Globe and Mail – [“B.C. seeks to decriminalize possession of illicit hard drugs in bid to slow worsening crisis”](#).

[15] City of Vancouver – [“Request for an exemption from the Controlled Drugs and Substances Act \(CDSA\) pursuant to section 56\(1\) that would decriminalize personal possession of illicit substances within the City of Vancouver”](#).

[16] City of Toronto – [“Report for Action – Actions to Respond to the Drug Poisoning Crisis in Toronto”](#); CBC – [“Toronto Board of Health votes to decriminalize possession of small amounts of illegal drugs”](#).

[17] CSE Financing Report November 2021.

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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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