

So Mushroom to Grow: Psilocybin and Canada's Regulatory Landscape

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As the cannabis industry continues to grow, Canada's capital markets have seen an increase in activity related to another substance that supporters are hopeful will eventually be removed from the list of controlled substances – *psilocybin*. Psilocybin is the active ingredient found in magic mushrooms. Proponents cite research demonstrating psilocybin's potential as a treatment for various mental illnesses. As Canadians become more informed about this research, we have seen an increased interest in investments related to psilocybin. Here, we outline Canada's current regulatory landscape for psilocybin and offer thoughts on the future of this emerging industry.

Potential Benefits of Psilocybin

Psychedelics, also known as hallucinogens, are psychoactive substances that produce changes in perception, mood and cognitive processes. While most people consider psychedelics to be a recreational drug and often associate them with the counterculture of the 1960s, psychedelics have a long history of medicinal use. However, due its negative public and political perceptions, little research occurred in this area for decades.^[1] Today, as mental health awareness grows, there is renewed interest in the use of psychedelics such as psilocybin for the treatment of a variety of mental illnesses.

Some studies have found that psilocybin can allow patients, with the help of trained therapists, to confront fears and feelings that are otherwise too traumatic.^[2] Other research has shown potential positive benefits for psilocybin use in suicidality, anxiety disorders, obsessive-compulsive disorder, alcohol dependence, tobacco cessation, and post-traumatic stress disorder, among others.^[3] One area of particularly strong focus has been on the potential use of psilocybin for relieving end-of-life distress for palliative patients. Proponents view psilocybin as providing relief from mental distress, particularly anxiety, when traditional treatment options fail for terminally ill patients as is often the case.^[4] This interest in psilocybin as a treatment also extends into the potential for treatment of the bereaved.

Regulation of Psilocybin in Canada

Despite promising research on its potential benefits, psilocybin remains a highly regulated, and generally illegal, substance in Canada. Psilocybin is regulated under the *Controlled Drugs and Substances Act* (the "CDSA").^[5] The CDSA divides these substances into schedules based on their potential for abuse or addiction and imposes penalties accordingly.^[6] Psilocybin falls under the category of a Schedule III controlled substance. The CDSA generally prohibits all uses of psilocybin unless use is allowed with an exemption.^[7] Violation of CDSA prohibitions can result in a fine or a term of imprisonment.^[8]

Exemptions to Psilocybin Prohibitions

Under the *Food and Drug Regulations*, authorization to possess psilocybin is given to, among others, licensed dealers and those

exempt by the Minister of Health under section 56 of the CDSA.[\[9\]](#)

Licensed Dealers

An individual or a corporation may apply to the federal Minister of Health for a dealer's license to be able to produce, assemble, sell, provide, transport, send, deliver, import, or export psilocybin.[\[10\]](#) The permitted activities for each licensed dealer depend on the type of license applied for. However, even with such a license, activities are heavily regulated.

Section 56 Exemptions

Under section 56 of the CDSA, persons in Canada may apply to Health Canada for an exemption from the prohibitions on psilocybin. The Minister of Health may grant a person an exemption if, in the Minister's opinion, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.[\[11\]](#)

In August 2020, for the first time, four terminally ill cancer patients in Canada were granted a section 56 exemption to use psilocybin for the treatment of end-of-life distress.[\[12\]](#) Since then, Health Canada has granted many more exemptions. Each exemption is valid for one year. In total, there have been 64 exemptions granted, 45 of which were given to patients. The other 19 exemptions were granted to health-care professionals who were given the right to possess and use psilocybin for professional training purposes. There are currently over 150 more exemption applications outstanding.[\[13\]](#)

The Future of Psilocybin

The numerous section 56 exemptions that Health Canada has granted for psilocybin use suggests that broader medical use of psilocybin may be on the horizon.

Perhaps unsurprisingly, these advances in our knowledge about psilocybin's potential as a treatment for mental illness have been accompanied by changes in the public perception of the substance. Recent surveys show that the majority of Canadians would support regulations for medical access to psilocybin and there are indications of bipartisan support for psilocybin-assisted treatments.[\[14\]](#) With support at an all-time high, industry groups are now focusing on introducing evidence-informed regulations to officials at Health Canada.[\[15\]](#) While it remains to be seen whether Health Canada will adopt the regulations that are being put forward for the medical use of psilocybin, experts across the country are optimistic that regulatory change is well on its way.

This optimism has also been reflected in Canada's capital markets. Since the beginning of 2020, over 20 psychedelics companies have been listed on Canadian stock exchanges, including a number of companies focused on the research and development of psilocybin-related products.[\[16\]](#) Additionally, this year, the world's first-ever psychedelics-focused exchange-traded fund ("**ETF**") was listed on the NEO Exchange in Canada. This ETF and corresponding Index includes multiple companies operating in the burgeoning psilocybin industry.[\[17\]](#)

Most recently, WeirFoulds assisted Psyence Group Inc. ("**Psyence**") (CSE:PSYG) in listing on the Canadian Securities Exchange ("**CSE**").[\[18\]](#) Psyence is a life science biotechnical company that is pioneering the use of natural psilocybin to heal psychological trauma and its mental health consequences, with a particular focus in the context of palliative care.[\[19\]](#) From a therapeutic perspective, Psyence has also embraced the complex interactions inherent in the very varied profile of molecules in different psilocybin strains. Psyence has international operations spanning throughout Canada, United States, United Kingdom, Jamaica, Lesotho, South Africa, and Australia.

The recent listing of Psyence on the CSE is evidence of the impact that psilocybin hopes to achieve globally. In Canada more specifically, this demonstrates a crucial step forward in the growing movement by both public and private companies, and the

Canadian government's support of research into psychedelic substances that may benefit people suffering from a variety of mental illnesses.

Conclusion

The legal and regulatory landscape surrounding psilocybin in Canada continues to change as research demonstrates its medical benefits. At the same, the public's view of psilocybin is changing. While psilocybin is currently used in limited medical circumstances, there is potential for its broader medical use through section 56 exemptions or other legislative or regulatory means.

While the public has recently demonstrated its comfort levels in capitalizing issuers in the psychedelics industry, psilocybin remains a highly regulated substance in Canada. Companies seeking to conduct business in this space must be aware of the complex regulatory landscape within which they must operate.

WeirFoulds will continue to monitor developments to the regulation of psilocybin. For more information on the topic discussed in this update, please contact [Dana Kriszenfeld](#) or a member of our [Securities Practice Group](#).

[1] David E. Nichols, "Psychedelics", (2016) 68:2 *Pharmacological Reviews* 164, online: <pharmrev.aspetjournals.org/content/68/2/264>.

[2] Curt Petrovich, "Health Canada dragging feet on approving magic mushrooms for therapeutic use, patients and advocates say", *CBC News* (27 July 2021), online <www.cbc.ca/news/canada/british-columbia/exemptions-psilocybin-therapy-1.6118296>.

[3] *Ibid*; Jeremy Daniel and Margaret Haberman, "Clinical potential of psilocybin as a treatment for mental health conditions" (2017) 7:1 *Mental Health Clin* 24, online: <www.ncbi.nlm.nih.gov/pmc/articles/PMC6007659/>.

[4] Camille Bains, "Patient hopes Canada will introduce regulations for psychotherapy with 'magic mushrooms'", *CBC News* (18 January 2021), online: <www.cbc.ca/news/canada/british-columbia/magic-mushrooms-regulations-canada-1.5877324>.

[5] *Controlled Drugs and Substances Act*, SC 1996, c 19, Schedule III [CDSA].

[6] Government of Canada, "Controlled Substances and Precursor Chemicals" (27 April 2020), online: <www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals.html>.

[7] CDSA, *supra* note 5 at ss 4-7.

[8] *Ibid*.

[9] *Food and Drug Regulations*, CRC, c 870, s J.01.004(1) (1978).

[10] *Ibid* at ss J.01.009-J.01.014.

[11] CDSA, *supra* note 5 at s 56.

[12] Bethany Lindsay, "4 Canadians with terminal cancer win the right to try magic mushrooms", *CBC News* (5 August 2020), online:

<www.cbc.ca/news/canada/british-columbia/magic-mushrooms-therapy-1.5675637>.

[13] Curt Petrovich, *supra* note 2; Curt Petrovich, “B.C. non-profit challenges Health Canada to tend 50-year prohibition on magic mushrooms”, *CBC News* (3 August 2021), online: <<https://www.cbc.ca/news/canada/british-columbia/therapsil-health-canada-psilocybin-1.6128123>>.

[14] Canadian Psychedelic Association, “New poll shows a strong base of Canadians overwhelmingly support controlled legal access to psilocybin-assisted therapy; Canadian Psychedelic Association responds with Memorandum of Regulatory Approval (MORA)”, *Canadian Psychedelic Association* (4 August 2021), online: <www.psychedelicaassociation.net/press-releases/new-poll-shows-a-strong-base-of-canadians-overwhelmingly-support-controlled-legal-access-to-psilocybin-assisted-therapy-canadian-psychedelic-association-responds-with-memorandum-of-regulatory-approval-mora> [CPA Press Release]; TheraPsil, “Public Opinion Towards Changes to Psilocybin Regulations in Canada”, *TheraPsil* (July 2021), online: <therapsil.ca/wp-content/uploads/2021/07/TheraPsil-2021-Public-Opinion-Survey-final.pdf>.

[15] *Ibid*, CPA Press Release; Curt Petrovich, *supra* note 14.

[16] Leila Rafi, Sasa Jarvis and Owen Gaffney, “The Canadian Capital Market is Psyched: An Update on the Growing Wave in the Psychedelics Industry”, *McMillan LLP* (12 May 2021), online: <mcmillan.ca/insights/the-canadian-capital-market-is-psyched-an-update-on-the-growing-wave-in-the-psychedelics-industry/>; Melissa Pistilli, “Psychedelics Stocks to Watch”, *Investing News Network* (9 August 2021), online: <investingnews.com/daily/life-science-investing/psychedelics-investing/psychedelics-stocks-to-watch/>.

[17] “Horizons ETFs Launches World’s First-Ever Psychedelic ETF on NEO Exchange”, *Business Wire* (27 January 2021), online: <www.businesswire.com/news/home/20210127005651/en/Horizons-ETFs-Launches-World%E2%80%99s-First-Ever-Psychedelic-ETF-on-NEO-Exchange>; “PharmaTher Added to the North American Psychedelics Index and First Psychedelic Exchange Traded Fund”, *Financial Post* (21 September 2021), online: <financialpost.com/globe-newswire/pharmather-added-to-the-north-american-psychedelics-index-and-first-psychedelic-exchange-traded-fund>.

[18] “WeirFoulds represents Psyence Group Inc. in listing on the CSE and subsidiary in \$9.3M private placement”, *WeirFoulds LLP* (26 January 2021), online <www.weirfoulds.com/weirfoulds-represents-psyence-group-inc-in-listing-on-the-cse-and-subsidiary-in-9-3m-private-placement>.

[19] “About Us” *Psyence*, online <psyence.com/psilocybin/>.

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