

RECENT UPDATES IN THE CANADIAN PSYCHEDELICS LANDSCAPE

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Introduction

Globally, the landscape governing psychedelics continues to evolve. Psychedelics have come to be viewed as a potential therapeutic or medical tool by both the general public and government. Over the last few years, Health Canada has continued to grant exemptions for use of psychedelics in certain settings and psychedelics are once again accessible through the Special Access Program (“**SAP**”). This bulletin seeks to summarize recent Canadian developments and builds on [our year in review article of 2021](#).

Regulatory Framework

Psychedelics are federally regulated under the *Controlled Drugs and Substances Act* (the “**CDSA**”)^[1] and most activities with controlled substances are prohibited, though there are limited permitted uses including with the use of exemptions.

Accessing Psychedelics

Section 56 Exemptions

Health Canada manages exemption requests to access psychedelics, which can be granted on an individual or class basis when the Minister of Health is of the opinion that the exemption is necessary for a medical or scientific purpose, or otherwise in the public interest (“**Section 56 Exemption**”).^[2]

In November 2021, the Province of British Columbia submitted a request to Health Canada for a province-wide Section 56 Exemption.^[3] On May 31, 2022, the Section 56 Exemption was granted, permitting adults in the province to possess prescribed amounts of opioids, methamphetamine, cocaine, and MDMA, without facing criminal charges.^[4] This was the first province-wide class exemption granted by Health Canada. British Columbia’s Section 56 Exemption was effective as of January 31, 2023 and will remain in effect until January 31, 2026.^[5]

On January 4, 2022, the City of Toronto submitted a similar application to the Minister of Health for a Section 56

Exemption, to decriminalize personal possession of all illicit substances listed in the CDSA.[6] Based on publicly available information, a response from Health Canada regarding the application remains outstanding.[7]

Clinical Trials

Practitioners wishing to obtain, possess, and administer controlled substances for clinical trials also require a Section 56 Exemption to allow them to do so.[8] On December 5, 2022, Health Canada released a notice to stakeholders delineating expected risk-management measures for clinical trials involving psychedelic-assisted psychotherapy.[9] The measures described are intended to reflect best practices emerging in literature and include the following:

- Therapists should be properly trained on evidence-informed protocols for psychedelic-assisted psychotherapy and licensed (in their jurisdiction, if applicable), though no strict guidelines are provided for the required training;
- During drug administration, at least two therapists should be present;
- The clinical environment should be psychologically safe for participants;
- Written informed consent must be obtained for participation in the trial, and if applicable, for physical touch during the session, recording of the session in part or full and in relation to the use of such recordings; and
- Any psychedelic drugs used must meet the standards in Health Canada's [Good Manufacturing Practices](#).

The above-outlined risk-management measures, or comparable alternative risk-management strategies that will be used in proposed clinical trials involving psychedelic-assisted psychotherapy should be included in the clinical trial application.[10]

Special Access Program

On January 5, 2022, amendments to the SAP came into force. The amendments, discussed in our [previous bulletin](#), restored the ability of health care professionals to request access to certain psychedelics to treat patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable or otherwise unavailable.[11] Since taking effect, at least one patient has claimed that Health Canada rejected her Section 56 Exemption application because she had not exhausted all other possible legal routes available to access psychedelics.[12] Unlike Section 56 Exemptions, which can be submitted directly by the patient, applications under the SAP must be submitted by a health care professional who is also responsible for obtaining and administering the drug, monitoring progress, and reporting on the results.[13]

Challenging Limits to Accessibility

On July 27, 2022, eight Canadians filed a challenge under the *Canadian Charter of Rights and Freedoms*

against the Government of Canada and the Minister of Health to increase access to psilocybin and psilocybin therapy.^[14] In the suit, the plaintiffs argue that current options to access psychedelics (in compliance with the CDSA) do not adequately serve patients' needs and infringe Section 7 of the Charter, which guarantees the right to life, liberty, and security of the person. Specifically, the plaintiffs claim that the current options are unreliable, accompanied by lengthy delays, invasive due to requirements to disclose personal and potentially incriminating information, and provide a time-limited solution only, among other concerns.^[15] As of August 2022, the Government of Canada had filed a statement of defence, among other things relying on its international treaty obligations in the regulation of controlled substances, and the lack of approval for any psilocybin based therapy in Canada.^[16] This matter has yet to be adjudicated, but we will continue to monitor its progress.

Updates in Provincial Regulation

On October 5, 2022, the Government of Alberta announced that it would become the first Canadian jurisdiction to regulate psychedelic-assisted therapy for the treatment of psychiatric disorders.^[17] An amendment to Alberta's *Mental Health Services Protection Regulation* took effect on January 16, 2023.^[18] As discussed in our recent bulletin, the amendments implemented a new framework to regulate and license health care providers in connection with administering psychedelics as part of treatment for mental health conditions. You can read more on this topic [here](#).

In December 2022, two medical doctors in Québec successfully billed the Province of Québec for the costs of psilocybin-assisted psychotherapy.^[19] Dr. Houman Farzin and Dr. Jean-François Stephan treated a patient who was granted a Section 56 Exemption in June of 2022.^[20] Following treatment, Dr. Stephan, supported by 15 colleagues and the governing body for general practitioners in Québec, the *Fédération des médecins omnipraticiens du Québec*, successfully advocated for psilocybin-assisted psychotherapy to be recognized as a medically insured service and for the government to allow the doctors to charge for the treatment.^[21]

Conclusion

The psychedelics landscape experienced notable developments over the last few years, which further support the view that controlled psychedelic substances have a potential positive role in medical treatment of disorders in Canada. As regulators continue to consider Section 56 Exemptions and non-conventional treatments involving psychedelics, and advocates utilize legal venues to seek to gain access to such treatments, we predict further impacts on the industry in the years to come. McMillan LLP will continue to monitor and report on these developments.

[1] *Controlled Drugs and Substances Act*, SC 1996, c 19.

[2] *Ibid*, s. 56(1).

- [3] British Columbia Ministry of Mental Health and Addictions, “[B.C. applies for decriminalization in next step to reduce toxic drug deaths](#)” (November 1, 2021), online: Government of British Columbia.
- [4] Health Canada, “[Subsection 56\(1\) class exemption for adults in the province of British Columbia to possess small amounts of opioids, cocaine, methamphetamine and MDMA](#)” (July 8, 2022), online: Government of Canada.
- [5] British Columbia Ministry of Mental Health and Addictions, “[BC’s Decriminalization Framework](#)” (February 15, 2023), online: Union of BC Municipalities.
- [6] Toronto Public Health, “[Request for exemption to the Controlled Drugs and Substances Act to allow for the possession of drugs for personal use in Toronto](#)” (January 4, 2022), online (pdf): City of Toronto.
- [7] Irem Koca, “[‘Indefensible’ that Toronto’s drug decriminalization request hasn’t been granted yet, advocate says](#)” (November 24, 2022), online: Toronto Star.
- [8] Health Canada, “[Application Form For An Exemption To Use A Controlled Substance For Clinical Studies](#)” (March 23, 2016), online: Government of Canada.
- [9] Health Canada, “[Notice to stakeholders: Health Canada’s expectations regarding risk-management measures for clinical trials involving psychedelic-assisted psychotherapy](#)” (December 5, 2022), online: Government of Canada.
- [10] *Ibid.*
- [11] Canada Gazette, Part II, Volume 156, Number 1, “[Regulations Amending Certain Regulations Relating to Restricted Drugs \(Special Access Program\): SOR/2021-271](#)” (January 5, 2022), online: Government of Canada.
- [12] Caroline Barghout & Kimberly Ivany, “[Terminal cancer patient denied magic mushrooms after Health Canada rule change](#)” (February 28, 2022), online: CBC News.
- [13] Health Canada, “[Health Canada’s special access programs: Request a drug](#)” (June 20, 2022), online: Government of Canada.
- [14] Statement of Claim dated July 27, 2022, Federal Court e-document T-1560-22.
- [15] *Ibid.*, at paras 31-68.
- [16] Statement of Defence dated August 26, 2022, Federal Court e-document T-1560-22.
- [17] Alberta Ministry of Health, “[Psychedelic assisted therapy](#)” (October 5, 2022), online (pdf): Government of Alberta.
- [18] *Mental Health Services Protection Regulation*, Alta Reg 114/2021.
- [19] AJ Herrington, “[Quebec Approves Health Coverage For Psilocybin Therapy](#)” (December 16, 2022), online: Forbes.
- [20] *Ibid.*
- [21] *Ibid.*

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A Cautionary Note

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