# BREAKING: Canada Opens New Legal Pathways For Access To Psychedelics Treatment With Psilocybin And MDMA

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January 5, 2022 1:44 pm





**In a groundbreaking decision, the Canadian government is changing the way patients can access psychedelic therapies with restricted drugs, including MDMA and psilocybin.**

Through an amendment to federal regulations, Health Canada is now **allowing physicians to request access to restricted drugs on behalf of patients** through the Special Access Program.



This program is meant to streamline access to special treatments for patients with serious or life-threatening conditions in instances where other therapies have failed or are unsuitable.

While the official communication made sure to note that “this regulatory change will not result in large-scale authorization for access to restricted drugs,” the event can be seen as an official acknowledgement of MDMA and psilocybin’s therapeutic potential and eventually lead to further decriminalization measures.

## The Amendment

In the Wednesday edition of the Canada Gazette, **the Canadian government published an amendment to the Food and Drug Regulations that now allows restricted drugs to be requested through Health Canada’s Special Access Program, which include psilocybin and MDMA**, among others.



The Special Access Program (SAP) allows healthcare practitioners to access drugs that have shown promise in clinical trials, or are approved in other countries, explained **Kathleen Marriner**, Media Relations Officer of the Communications and Public Affairs Branch of Health Canada.

This means that practitioners will, on behalf of patients with serious or life-threatening conditions, be able to request otherwise restricted drugs through the SAP in instances where other therapies have failed, are unsuitable or are not available in Canada.

“There has been emerging scientific evidence supporting potential therapeutic uses for some restricted drugs, most notably psychedelic restricted drugs such as MDMA and psilocybin,” noted the Canadian Government’s official communication.

The Gazette acknowledged that, since restricted drugs were banned from the SAP, the science pertaining to the efficacy and safety of some of them has continued to advance, with several now demonstrating potential therapeutic uses, **including in Phase II and Phase III clinical trials (https://www.benzinga.com/markets/cannabis/21/08/21881619/psychedelics-research-fyi-every-clinical-trial-underway-right-now-involving-public-and-private-c)**.

## What Is The Special Access Program And How Does It Work?

Health Canada’s Special Access Program was created to allow healthcare practitioners to access drugs that have shown promise in clinical trials, or are approved in other countries, for patients with serious or life-threatening conditions where conventional treatments have failed, are unsuitable or are not available in Canada.

“Each request is assessed on a case-by-case basis, taking into consideration the level of evidence available on the use, safety and efficacy of the drug for the patient’s specific condition,” Marriner explained in an email.

“Requests to the Special Access Program are normally only considered when positive results of Phase II or Phase III clinical trials are already available,” according to the Gazette.

Only practitioners and pharmacists are allowed to request drugs through the SAP. “**Access to SAP is available 24 hours a day, 365 days a year, and Health Canada tries to contact the requester within 1 working day of receipt**,” Marriner added.

Until now, there have been only two ways patients in Canada were able to access psilocybin treatment in a legal context. One involves participating in a clinical trial, which in Marriner’s words is “the most appropriate pathway to allow access to experimental products, including psilocybin, with a possible medical benefit, that have not yet undergone the rigorous, science-based review process to be authorized as marketed drugs.”



However, **vacancies on clinical trials are limited** and only exist in specific locations and time periods.

“While clinical trials remain the best mechanism to authorize the sale of restricted drugs (or any other unapproved drug) for the treatment of patients, there may be situations where a patient is unable to participate in one. For example, there may not be any clinical trials currently recruiting for a specific drug or in a specific area of the country,” wrote the Gazette.

**A second means to access psilocybin** is through section 56 exemptions: a process that allows patients to personally request access to restricted drugs like psilocybin via the Health Minister.

**Since August 2020 (https://www.benzinga.com/markets/cannabis/20/08/16992761/psyched-canada-makes-psilocybin-history-usona-publishes-new-method-for-psilocybin-synthesis)**, about four dozen patients have been granted exemptions to access psilocybin treatment through a personal written authorization from the Health Minister herself, in a process that **has been described by advocates (https://www.benzinga.com/markets/cannabis/21/05/21221709/canada-is-seeking-to-expand-access-to-psilocybin-but-legalization-appears-to-be-farther-down-the)** as “a stopgap solution,” which leaves many patients in need out of the system.

The initial requests to use psilocybin under section 56 exemptions were granted only after more than 100 days of waiting. Taking this measure into consideration, allowing psilocybin and MDMA to be a part of the Special Access Program, appears to be a clear step toward easing access to these treatments.

## What Does This Mean For Psilocybin And MDMA Therapy In Canada?

In December 2020, Health Canada opened a consultation targeted at health care professionals and organizations, researchers and academics, licensed dealers, as well as the general public, requesting them to assess the amendment that was finally approved on Wednesday. Health Canada received comments from 392 unique respondents, the vast majority of whom are members of the public.

“Overall, nearly all comments were supportive of the proposed regulatory amendments and/or increasing access to psychedelic substances more broadly. The Department received very little opposition to the proposal, making up less than 2% of all responses,” the Gazette wrote.

“Over 80% of all respondents associated Health Canada’s proposal with increasing access to psychedelic restricted drugs (e.g. MDMA, psilocybin, LSD, DMT), often for the treatment of various conditions, most notably mental health disorders.”

**While public opinion towards opening access to psychedelic therapies in Canada is strong, the regulating body made sure to note that the new amendment does not open a path toward the legalization or decriminalization of these drug therapies.**

**Marriner told Benzinga** that “in Canada, the sale and possession of mushrooms containing psilocybin remain illegal under the Controlled Drugs and Substances Act and Health Canada has not authorized any products containing psilocybin under the **Food and Drugs Act (https://laws-lois.justice.gc.ca/eng/acts/f-27/page-1.html)** and the **Food and Drug Regulations (https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/frequently-asked-questions-food-drug-regulations.html)**.”

“The outcomes of this consultation suggested **there is strong public interest in the use of psychedelic restricted drugs for therapeutic purposes**,” reported the Gazette, however noting that “the regulatory proposal was commonly misinterpreted to mean that there would be guaranteed access to psychedelic restricted drugs through the Special Access Program, and/or that access would be granted to a large number of individuals.”



The Gazette stressed that “the regulatory amendments will not create large scale access to restricted drugs and they do not signal an intent towards the decriminalization or legalization of restricted drugs. The Special Access Program is for emergency treatment only.”

only.

Only the execution of these new measures will provide an answer to whether they indeed improve access to psilocybin and MDMA in Canadian patients. However, the allowance of a new pathway for requesting access could catalyze the need for a more sustainable and satisfactory approach to these medicines.

In 1999, section 56 exemptions allowed Canadians to first use cannabis legally for medical purposes. An **overflow in exemption requests** was one of the driving forces behind Canada's **decision to legalize cannabis for medical purposes in 2001**, which led to the **full legalization (https://www.benzinga.com/government/18/06/11911059/canada-legalizes-recreational-marijuana-nationwide-beginning-oct-17-expert)** of adult-use cannabis in 2018.

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