

**Written Submission for the Pre-Budget Consultations in Advance of the  
Upcoming Federal Budget**

By: PsyCan



<https://psychedelicscanada.org/>

## List of Recommendations

- **Recommendation:** The Government of Canada should realize significant legal and administrative cost savings and ease regulatory burden by creating a section 56 class exemption under the Controlled Drugs and Substances Act allowing any qualified mental health professional with prescribing powers to prescribe, and any controlled substances licensed pharmacist to dispense, MDMA or psilocybin for qualifying mental health conditions.

Numerous landmark scientific articles demonstrate the safety and efficacy of psychedelic drugs in clinical trials in mental health conditions such as Anxiety, Major Depressive Disorder (MDD), Treatment Resistant Depression (TRD), Alcohol Use Disorder (AUD), Post-Traumatic Stress Disorder (PTSD), and Opioid Use Disorder (OUD), among others. Results from most trials show psychedelic-assisted psychotherapy (PAP) can be faster and more effective than current treatments<sup>1</sup> — representing significant potential healthcare cost savings.

Health Canada’s Special Access Program (SAP) has, since 2022, allowed healthcare practitioners to request access to therapeutic psychedelics such as psilocybin and MDMA on a case-by-case basis to treat patients with serious or life-threatening conditions when conventional treatments have failed, are unsuitable, or unavailable in Canada.<sup>2</sup>

An August 2025 release of SAP records under the Access to Information Act showed psilocybin and MDMA approvals dropped dramatically since last year, from ~65% to ~30%.<sup>3</sup> Testimonials from failed SAP applicants suggest each rejection running 15 pages on average, often followed by mandamus applications that are being accepted by the government following extensive legal back-and-forth. Courts have also set aside Health Canada refusals and forced redeterminations, creating additional administrative and legal workloads.<sup>4</sup>

1. Total number of SAP applications submitted involving the use of psilocybin or MDMA, broken down by substance and by quarter or year.

Year	Number of Requests Received (MDMA)	Number of Requests Received (Psilocybin)
2022	16	71
2023	35	152
2024	54	177
2025	21	71
<b>Total</b>	<b>126</b>	<b>471</b>

2. Number of SAP applications that were approved, denied, withdrawn, or deemed incomplete for each substance.

Decision	Number of Requests (MDMA)	Number of Requests (Psilocybin)
Authorized	81	308
Cancelled	3	5
Denied	1	18
Incomplete	27	95
Withdrawn	14	45
<b>Total</b>	<b>126</b>	<b>471</b>

All ministries have been asked to find 7.5% from program spending for the 2026-2027 fiscal year, followed by 10% in the next year, and 15% in the year after.<sup>5</sup>

<sup>1</sup> Psychedelic-Assisted Psychotherapy: A Paradigm Shift in Psychiatric Research and Development. Eduardo Ekman Schenberg. *Frontiers in Pharmacology*. 2018; 9: 733.

<sup>2</sup> Notice to stakeholders: Requests to the Special Access Program (SAP) involving psychedelic-assisted psychotherapy. Health Canada. February 27, 2023.

<sup>3</sup> Access to Information Act request A-2025-000569. Health Canada. August 13, 2025.

<sup>4</sup> Judicial review decision (T-1881-23). Federal Court of Canada, Trial Division. June 2025. 36 pages. A decision concerning Dr. Davenport’s request under the Special Access Program (SAP) for psilocybin to treat cluster headaches, highlighting administrative review of the SAP redetermination. <https://judicialreviewlaw.ca/docs/T-1881-23%20-%20Decision.pdf> | Letter to Dr. Davenport (redacted). Health Canada, Pharmaceutical Drugs Directorate. June 7, 2024. A five-page letter regarding the redetermination of J.L.’s SAP request for psilocybin following a Federal Court decision, including Health Canada’s confirmation of additional evidence received late in the process. <https://static1.squarespace.com/static/601dd5fc10894c548327a294/t/666a1cb90cc2144755e6e319/1718230201622/Letter+to+Dr.+Davenport+%28June+7%2C+2024%29+-+redacted.pdf>

Fighting back on SAP and clinical trial applications is costing Health Canada significantly in time and labour only to deny patients access to medication requested by their doctors that have shown significant clinical efficacy in combatting mental health conditions. This runs contrary to parliamentary recommendations, particularly the Senate's *The Time is Now* report.<sup>6</sup>

Some jurisdictions, such as Australia and New Zealand, have approached this issue by creating permissions for any qualified mental health professional with prescribing powers to access medications such as MDMA or psilocybin for their patients in a responsible matter, but not by creating additional burden for their respective health regulators. Other jurisdictions, like Germany, Switzerland, and several U.S. states (e.g. Colorado, Oregon, New Mexico) have taken similar steps to expand access.

**Therefore, the Government of Canada should realize significant legal and administrative cost savings and ease regulatory burden by creating a section 56 class exemption under the Controlled Drugs and Substances Act allowing any qualified mental health professional with prescribing powers to prescribe, and any controlled substances licensed pharmacist to dispense, MDMA or psilocybin for qualifying mental health conditions.**

Provinces have already proven they have the foresight to pass complimentary legislation; Alberta passed psychedelic-assisted psychotherapy regulations in 2023, and Quebec already established billing codes for psychedelic-assisted therapy. Case-by-case SAP requests for potentially life-saving psilocybin and MDMA therapies are slow, unpredictable, expensive and fundamentally ill-suited to addressing the current mental health and addiction crises.

### **The Broader Costs of Inaction to Government and Economy**

The broader costs of inaction on this file are enormous. A 2024 report from the Canadian Mental Health Association revealed that 1 in 5 Canadians suffer from mental illness, while 2.5 million suffer inadequate access to treatment.<sup>7</sup> More than 50,000 Canadians die each year from substance use and over 3 million

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<sup>5</sup> Canadian government seeks billions of dollars of savings over next three years. Reuters. July 7, 2025. <https://www.reuters.com/world/americas/canadian-government-seeks-billions-dollars-savings-over-next-three-years-2025-07-07/>

<sup>6</sup> The Time is Now: Granting equitable access to psychedelic-assisted therapies. Senate of Canada. November 8, 2023. <https://sencanada.ca/en/info-page/parl-44-1/veac-psychedelic-therapies/>

<sup>7</sup> The state of mental health in Canada? It's alarming, a new CMHA report finds. CMHA Ottawa. November 20, 2024. <https://ottawa.cmha.ca/the-state-of-mental-health-in-canada-2024/>

Canadians use substances problematically.<sup>8</sup> Illicit psychedelic retailers currently operate ubiquitously online and even on main streets in over 1/3rd of Canada's major urban areas.<sup>9</sup>

Mental illness and addiction drain nearly \$100 billion annually from the Canadian economy due to hospitalization, law enforcement, lost productivity and other related impacts.<sup>10</sup> That price pales in comparison to what it will cost to meet treatment needs with status-quo programs. We simply don't have the beds. Building out that infrastructure will take billions of additional dollars that no government can afford to spend and will take years that those suffering cannot afford to wait. Expanding access to proven psychedelic therapies can save billions of dollars annually.

Canada is also home to the world's most promising psychedelic medicine companies and has the opportunity to become a global leader in this emerging sector. The psychedelic medicines industry is projected to be worth over 8 billion USD by 2028.<sup>11</sup> This could mean thousands of new jobs, billions of dollars in new investment, an expanded tax base, and myriad indirect economic multipliers across the country. However, Canada risks losing its lead as it is surpassed by other jurisdictions (e.g. psilocybin is under review for potential reclassification at the U.S. Department of Health and Human Services). At a moment where diversification and domestic economic development are paramount, it would be negligent for the government to not support (or at least not continue to hinder) such an innovative and valuable home-grown industry.

In a time of political division, the vast majority (~68%) of citizens are "open to Canadians being allowed to use mushroom-based psilocybin-assisted psychotherapy", rising to 84% for people who are suffering from a terminal illness.<sup>12</sup> The Government of Canada should reflect society's consensus and act

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<sup>8</sup> Canadian Substance Use Costs and Harms 2007–2020. Canadian Centre on Substance Use and Addiction. 2023. <https://csuch.ca/assets/documents/reports/english/Canadian-Substance-Use-Costs-and-Harms-Report-2007-2020-en.pdf> | Mental and substance use disorders in Canada. Statistics Canada. November 27, 2015. <https://www150.statcan.gc.ca/n1/pub/82-624-x/2013001/article/11855-eng.htm>

<sup>9</sup> Psilocybin Dispensaries and Online Health Claims in Canada. JAMA Network Open. April 1, 2025. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2832050>

<sup>10</sup> Making the Case for Investing in Mental Health in Canada. Mental Health Commission of Canada. 2013. [https://www.mentalhealthcommission.ca/wp-content/uploads/drupal/2016-06/Investing\\_in\\_Mental\\_Health\\_FINAL\\_Version\\_ENG.pdf](https://www.mentalhealthcommission.ca/wp-content/uploads/drupal/2016-06/Investing_in_Mental_Health_FINAL_Version_ENG.pdf) | Canadian Substance Use Costs and Harms 2007–2020. Canadian Centre on Substance Use and Addiction. March 29, 2023. <https://www.ccsa.ca/en/lost-productivity-due-substance-use-cost-canadian-economy-224-billion-new-report>

<sup>11</sup> Psychedelic Therapeutics Market worth \$8.31 billion by 2028 - Exclusive Report by InsightAce Analytic. InsightAce Analytic. July 18, 2022. <https://www.prnewswire.com/news-releases/psychedelic-therapeutics-market-worth--8-31-billion-by-2028---exclusive-report-by-insightace-analytic-301588119.html>

<sup>12</sup> Social acceptability of psilocybin-assisted therapy for existential distress at the end of life: A population-based survey. Palliative Medicine. January 23, 2024. <https://pubmed.ncbi.nlm.nih.gov/38253521/>

on this budgetary, economic, and moral imperative. We have the science and regulatory tools. What we need now is political will.