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The promise and challenges of psychedelic-assisted therapy: lessons from Canada's Special Access Program

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To realize the potential of emerging psychedelic therapies, clinical and systemic obstacles must be surmounted.

Psychedelic-assisted psychotherapy (PAP) has been heralded as a potentially revolutionary advancement in mental health treatment with transformative promise for conditions that have long defied conventional therapies[1,2]. Substances such as psilocybin have demonstrated benefits in clinical trials pairing them with psychological support, fueling optimism for the treatment of refractory depression[3,4], substance use disorders[5,6] and existential distress[7].

In January 2022, Canada's Special Access Program (SAP) broke new ground by allowing healthcare providers to request restricted psychedelic drugs on a clinical basis — that is, outside research trials — for patients with serious or life-threatening conditions, if conventional treatments have failed, are unsuitable or are unavailable[8]. Health Canada's SAP program allows healthcare practitioners to request limited access to pharmaceuticals that have not been nationally authorized for sale. SAP drugs are typically in development or have otherwise not completed the formal study process required for licensing[9]. They are approved on a drug-by-drug basis under Health Canada's discretionary authority, with no explicit thresholds for determining whether the available evidence for efficacy is sufficient. Similar pathways exist in multiple countries, including the Food and Drug Administration's 'Right to Try' Expanded Access programs in the USA.

As discussed in this Comment, Canada's SAP provides a rare and unprecedented opportunity to examine real-world data on the implementation of psilocybin-assisted therapy. This article presents the first published data on the program, revealing critical insights into how psychedelic therapies were being accessed and utilized in Canada in the past 3 years. The data underscore clashes between the promise of psychedelic therapies and the practical barriers facing their potential clinical employment in Canada's SAP and more broadly.

Promises meet practical realities

The clinical potential of psychedelics has often been linked to their ability to induce non-ordinary states of consciousness, which may facilitate psychological insights and emotional breakthroughs. This, along with growing scientific interest in their biological effects that may occur independently of the psychedelic experience — such as serotonergic modulation, neuroplasticity and anti-inflammatory processes — has fueled enthusiasm for their therapeutic application. However, translating these findings into clinical practice remains fraught with challenges[2,10].

In response to a formal Access to Information request sent by the authors, Health Canada and the Public Health Agency of Canada Program Office reported that between January 2022 and December 2024, the SAP processed 436 requests for clinical access to psilocybin nationwide, primarily for the treatment of major depressive disorder (MDD) and end-of-life distress (Table 1). Of these, only 304 (69.7%) were authorized, including 41 for MDD and 33 for end-of-life distress in 2022; 86 and 37, respectively, in 2023; and 80 and 25 in 2024. Only one request, which was denied, was made for the treatment of a substance use disorder (alcohol use). Gender distribution was relatively balanced across indications, with slightly more approvals granted to males for depression and females for end-of-life distress (Table 1).

Approval rates significantly declined from 2022 to 2024 according to χ^2 testing ($\chi^2 = 18.12$, $P < 0.001$). In 2022, 74 of the 90 (82%) requests were approved, followed by 123 out of 165 (74.5%) in 2023 and 107 out of 181 (59.1%) in 2024, even though the number of overall requests remained stable. Additional χ^2 analyses revealed significant differences in approval rates between MDD and end-of-life distress in both 2023 and 2024, with end-of-life distress receiving significantly higher approval rates (Table 1).

Notably, to our knowledge, there have been no major regulatory changes, new safety concerns or formalized shifts in the SAP's clinical indications or in screening and evaluation criteria since 2022. The falling approval rates may thus reflect challenges and barriers facing the implementation of psychedelic therapies in the SAP and potentially beyond, even when they are deployed in a public-payer healthcare system where physicians can be specifically reimbursed for related clinical acts (at least in one Canadian province, Quebec).

Challenges with the Special Access Program

The path to implementing PAP specifically through compassionate access programs such as Canada's SAP — a program that, notably, was not originally developed for psychedelic therapies — is marked with interconnected barriers to adoption. The following sections present potential explanations for the reported data trends based on pre-existing literature and informed by the authors' direct experiences providing PAP through the SAP.

Regulatory complexity. One notable challenge is the program's regulatory complexity: SAP applications have stringent requirements for extensive documentation, including failures of conventional therapies and evidence for PAP's safety and efficacy for an individual patient. When an application is flagged as incomplete, providers must resubmit with even more detailed justifications and clinical information, adding further complexity and delays to an already demanding process. Although vital for ensuring safety, rigorous case-by-case approval processes may deter clinicians from engaging with the program. Indeed, the increasing number of incomplete applications and withdrawals, along with the unchanging number of requests between 2023 and

Table 1 | Statistics on access to psilocybin under the SAP of Health Canada (January 2022–December 2024)

Year (no. requests)	Decision	Clinical indication	Approval rate (%)		Reasons for non-authorization	Gender
			By indication	Global		
2022 (*n* = 90)	Authorized (*n* = 74)	MDD (*n* = 41)	78.8%	82.2%		M (*n* = 20), F (*n* = 21)
		End-of-life distress (*n* = 33)	91.7%			M (*n* = 16), F (*n* = 17)
	Not authorized[a] (*n* = 16)	MDD (*n* = 11)			I (*n* = 7), W (*n* = 4)	M (*n* = 5), F (*n* = 6)
		End-of-life distress (*n* = 3)			I (*n* = 2), W (*n* = 1)	M (*n* = 3)
		Cluster headaches (*n* = 1)			W (*n* = 1)	F (*n* = 1)
		Post-traumatic stress disorder (*n* = 1)			C (*n* = 1)	M (*n* = 1)
2023 (*n* = 165)	Authorized (*n* = 123)	MDD (*n* = 86)	74.8%[a]	74.5%		M (*n* = 43), F (*n* = 40), O (*n* = 3)
		End-of-life distress (*n* = 37)	90.2%			M (*n* = 15), F (*n* = 22)
	Not authorized (*n* = 42)	MDD (*n* = 29)			I (*n* = 14), W (*n* = 11), D (*n* = 4)	M (*n* = 16), F (*n* = 12), N (*n* = 1)
		End-of-life distress (*n* = 4)			I (*n* = 1), W (*n* = 3)	M (*n* = 1), F (*n* = 3)
		Cluster headaches (*n* = 5)			I (*n* = 2), W (*n* = 1), D (*n* = 2)	M (*n* = 3), N (*n* = 2)
		Post-traumatic stress disorder (*n* = 4)			C (*n* = 2), W (*n* = 2)	M (*n* = 1), F (*n* = 3)
2024 (*n* = 181)	Authorized (*n* = 107)	MDD (*n* = 80)	56.7%[a]	59.1%		M (*n* = 43), F (*n* = 37)
		End-of-life distress (*n* = 25)	80.6%			M (*n* = 12), F (*n* = 13)
		Migraine attack (*n* = 2)	25.0%			M (*n* = 2)
	Not authorized (*n* = 74)	MDD (*n* = 61)			I (*n* = 40), W (*n* = 16), D (*n* = 5)	M (*n* = 35), F (*n* = 23), O (*n* = 3)
		End-of-life distress (*n* = 6)			I (*n* = 3), W (*n* = 2), D (*n* = 1)	M (*n* = 4), F (*n* = 2)
		Cluster headaches/migraine attack (*n* = 6)			I (*n* = 4), D (*n* = 2)	M (*n* = 2), F (*n* = 4)
		Alcohol use disorder (*n* = 1)			D (*n* = 1)	O (*n* = 1)
2022–2024 (*n* = 436)	Authorized (*n* = 304)	MDD (*n* = 207)	67.2%[a]	69.7%		M (*n* = 106), F (*n* = 98), O (*n* = 3)
		End-of-life distress (*n* = 95)	88.0%			M (*n* = 43), F (*n* = 52)
		Migraine attack (*n* = 2)	14.3%			M (*n* = 2)
	Not authorized (*n* = 132)	MDD (*n* = 101)			I (*n* = 61), W (*n* = 31), D (*n* = 9)	M (*n* = 56), F (*n* = 41), O/N (*n* = 4)
		End-of-life distress (*n* = 13)			I (*n* = 6), W (*n* = 6), D (*n* = 1)	M (*n* = 8), F (*n* = 5)
		Cluster headaches/migraine attack (*n* = 12)			I (*n* = 6), W (*n* = 2), D (*n* = 4)	M (*n* = 5), F (*n* = 5), N (*n* = 2)
		Post-traumatic stress disorder (*n* = 5)			C (*n* = 3), W (*n* = 2)	M (*n* = 2), F (*n* = 3)
		Alcohol use disorder (*n* = 1)			D (*n* = 1)	O (*n* = 1)

[a]$P < 0.05$ from χ^2 tests comparing approval rates for major depressive disorder (MDD) and end-of-life distress. Reasons for non-authorization as provided by Health Canada are the following: incomplete (I), the SAP form is incomplete or unclear; cancelled (C), request cancelled because the manufacturer is unable to provide access to the drug through SAP or the drug is not marketed in Canada; withdrawn (W), the health care professional who made the request has withdrawn the application; denied (D), the information does not meet SAP criteria. F, female; M, male; N, null (for example, the request either requires more information from the physician or is still under review by the SAP); O, other.

2024 — despite greater public and professional awareness — suggest that administrative hurdles may be limiting uptake.

Potential indication-specific variability. Another challenge is the lack of clarity and consistency in regulatory standards over time and between indications. Approval rates for end-of-life distress have remained relatively consistent and higher than those for MDD, which has seen sharp declines in SAP approval rates over the past 2 years (Table 1). These data potentially reflect more sustained regulatory comfort with palliative indications, for which clinical urgency is high and potential harms may be more acceptable, and/or evolving concerns about depression as an indication. In any case, the SAP's limited transparency and lack of indication-specific guidance or application criteria are important sources of confusion among clinicians.

Wider challenges in delivering psychedelic therapies

Although the SAP is one nation's unique program for potential access to psychedelic therapies, many of its challenges may be generalizable to other exceptional access programs and, indeed, to potential post-approval access pathways.

Lacking training and expertise. There are no widely accepted trainings, certifications or standardized accreditation processes for the provision of psychedelic therapies or for making SAP access requests—any

Canadian licensed physician or nurse practitioner may submit a SAP application. Psychedelic therapies, however, are complex interventions that requires clinical expertise in their pharmacological effects as well as the capacity to create psychologically safe environments for (potentially) therapeutic experiences[11]. Despite the growing interest in psychedelics, few practitioners have received formal training in this area and possess the required knowledge; training opportunities remain limited across Canada, and psychedelics are rarely included in standard medical education curricula[12]. Addressing the current issues with robust training programs and continuing medical education will be a crucial challenge for the eventual implementation of psychedelic therapies following potential market approvals, which may or may not be facilitated by changes in post-approval landscapes[13].

Resource-intensive nature of PAP. The resource-intensive nature of PAP presents considerable logistical and infrastructural challenges. Lengthy treatment sessions (on the order of 6–10 hours), which require controlled environments for safety and efficacy[1,14], necessitate substantial investments in dedicated treatment centers or clinical spaces. The high cost and logistical complexity of these requirements make PAP difficult to scale, especially in public healthcare systems.

Limited availability of GMP-compliant substances. Another major obstacle is the limited availability of Good Manufacturing Practices (GMP)-compliant psychedelic substances, such as psilocybin. Ensuring that substances meet GMP standards is critical for patient safety, but the scarcity of certified suppliers adds logistical hurdles for clinicians. Importing or obtaining these substances often requires additional permits and coordination with licensed manufacturers, further complicating the process. In the past 2 years, more than 2% of SAP requests were not authorized because the manufacturer was unable to provide access to the drug. Addressing this bottleneck will require expanding the number of certified suppliers and streamlining supply chain logistics.

Stigma and public perception. Despite growing scientific validation of psychedelics, and evidence that psychedelic therapies can be effective outside clinical trials[10], another important barrier to their adoption is stigma[15]. Their past and current associations with recreational use, and their controlled-substance statuses in many jurisdictions, undoubtedly contribute to hesitancy among healthcare providers, patients and institutions[11]. This may help explain the disconnect between research evidence and clinical update seen in the SAP data for substance use disorders: despite promising clinical trial data for the utility of psilocybin in treating alcohol use disorder and tobacco use disorder, only one SAP request was submitted for either indication over the 3-year period studied. Public and professional education campaigns that increase knowledge of the therapeutic potential and safety profiles of psychedelics, without understating their risks, will be critical for overcoming overly negative or positive views about their effects.

Medicolegal responsibilities and the lack of standards of care. One of the most pressing barriers to PAP implementation is the lack of established standards of care. Unlike conventional treatments, psilocybin-assisted therapy lacks clear guidelines about fundamental aspects such as the required amount of psychotherapy, specific outcome measures and therapeutic protocols. There is no consensus on the number of preparatory or integration sessions required, the duration of psychological support during dosing or the use of validated tools to assess treatment outcomes. This absence of standardization poses significant medicolegal risks. If a patient experiences harm — whether psychological distress, adverse drug reactions or failure to achieve therapeutic benefits — it is difficult to determine whether the care provided was appropriate. Without defined benchmarks, courts and regulatory bodies may struggle to evaluate whether clinicians acted responsibly or negligently. Until such standards are established, clinicians must therefore proceed cautiously, thoroughly documenting their decision-making processes and adhering closely to available best practices. Establishing robust medicolegal frameworks will be critical for legitimizing PAP as a mainstream therapeutic option while protecting both patients and providers.

Broader lessons learned

The SAP in Canada, although embedded in a uniquely Canadian regulatory and healthcare context, can serve as a case study for other countries developing regulatory pathways for psychedelic therapy — exceptional or otherwise. Experiences of the program highlight the need to balance rigorous safety protocols with practical accessibility and transparency. Regulatory processes that are opaque, complicated or applied inconsistently can disincentivize clinicians and lead to the exclusion of potentially suitable patients — particularly those without the financial or social capital to navigate complex pathways, as has already been observed in clinical research[16]. Without deliberate efforts to reduce administrative complexity and promote equity, psychedelic therapies may become accessible to only a privileged few.

Implementing PAP will thus require systemic investment across multiple levels. Clearer regulatory guidance is needed to support clinician decision-making, along with nationally recognized standards for training, certification and continuing medical education. Medical schools and residency programs all have critical roles in preparing the next generation of providers to deliver PAP safely and ethically. National guidelines and professional frameworks can further legitimize these novel therapies and reduce medicolegal uncertainties. Additionally, centers of excellence that bring together research, treatment, education and direct communication with regulators could serve as much-needed hubs for clinical innovation and knowledge translation. Such institutions could implement research projects such as prospective cohort studies that systematically track application patterns — including geographic and institutional origin and provider characteristics — and facilitate evidence-based development of best practices and public education towards translating these relatively niche treatments to successful integration in real-world care systems.

Conclusion

The static demand and declining approval rates observed for psychedelic therapies in Canada's SAP, 2 years after the first approvals, underscore barriers to implementing PAP in real-world and challenges in balancing risks and benefits. These challenges, ranging from regulatory hurdles to training deficits and infrastructure gaps, highlight work that is necessary for psychedelic therapies to emerge as viable clinical options. As interest in psychedelics grows across the globe, Canada's SAP may offer critical insights for other jurisdictions exploring or implementing similar frameworks that more effectively balance the promise and real-world complexity of psychedelic therapies.

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N.G., L.P., K.T.G. and M.D. had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. N.G. and M.D. conceived and designed the study. All authors contributed to the acquisition, analysis or interpretation of the data. N.G. and M.D. drafted the manuscript, and all authors critically revised it for important intellectual content. M.D. conducted the statistical analysis. N.G. and M.D. provided administrative, technical or material support, and the study was supervised by N.G., K.T.G. and M.D.

Competing interests

The authors declare no competing interests.

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