



Psychedelic Research Snapshot

# **The Promise and Challenges of Psychedelic- Assisted Therapy: Lessons from Canada's Special Access Program**





## Objectives

To assess how psychedelic-assisted psychotherapy (PAP), particularly psilocybin-based, is accessed and utilized under Canada's Special Access Program (SAP).

To examine barriers in translating PAP from clinical trials into real-world practice.

To derive broader lessons for implementing psychedelic therapies through exceptional regulatory pathways.



**MAPS**  
CANADA 



# Background



## What is SAP?

- Canada's Special Access Program (SAP) allows physicians to request restricted, unapproved drugs for serious conditions when standard treatments fail.
- In January 2022, SAP began allowing access to psychedelics like psilocybin outside clinical trials.

## What conditions is SAP for?

- SAP is aimed at conditions like major depressive disorder (MDD) and end-of-life distress.

## Results

436 total requests for psilocybin-  
assisted therapy 304 authorized  
(69.7%)

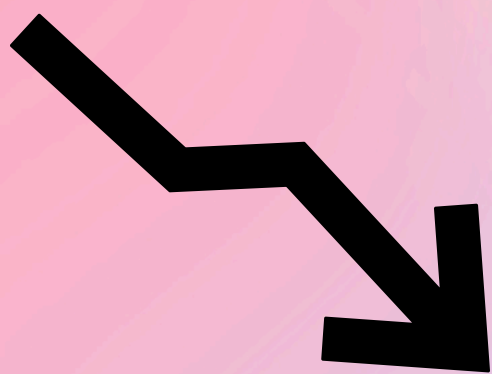
### Indications approved:



MDD (67.2% approval)

End-of-life distress (88% approval)

### Approval rates declined over time:



2022: 82%

2023: 74.5%

2024: 59.1%

Only 1 request submitted for  
substance use disorder (alcohol) —  
denied

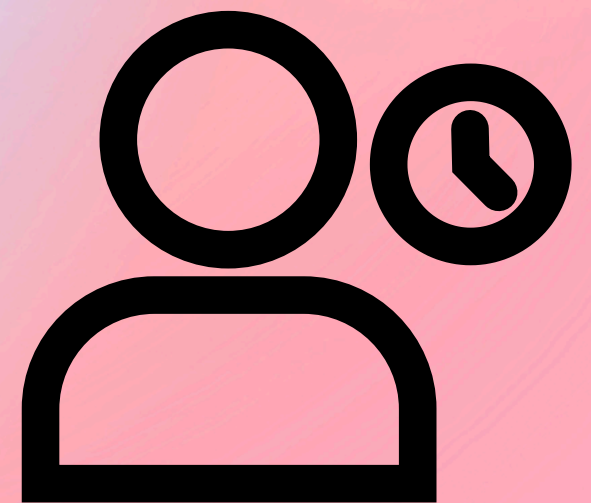
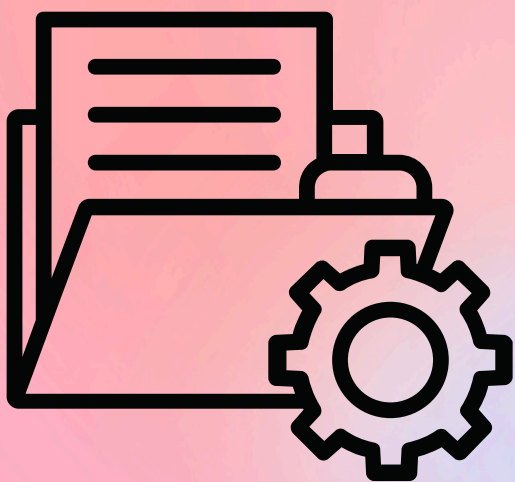


# Challenges & Barriers

**Regulatory Burden:** SAP applications require extensive documentation; rising rate of incomplete/withdrawn applications.

**Training Gaps:** Few providers have formal education in PAP; no national accreditation system.

**Infrastructure Demands:** Long session times (6–10 hours) and controlled environments needed.



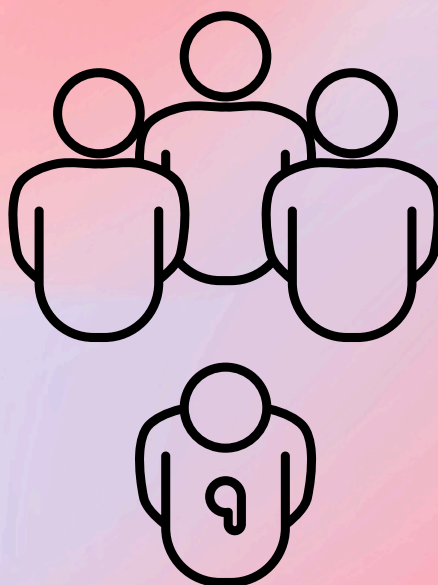
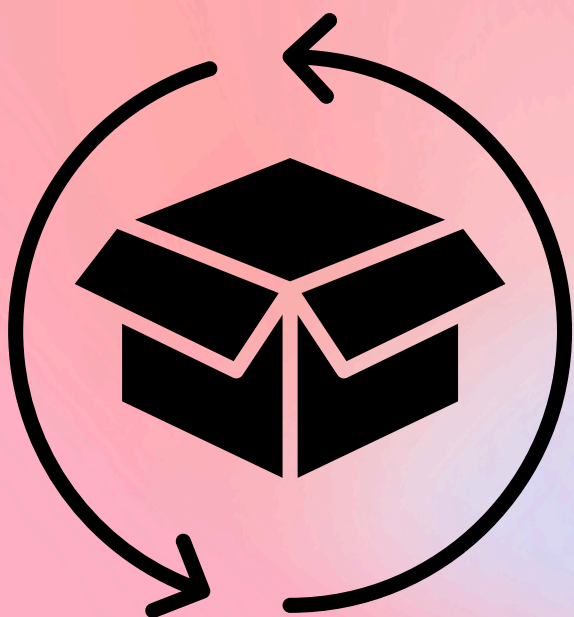


## Challenges & Barriers

**Drug Supply Issues:** Limited access to GMP-compliant psilocybin and mdma

**Stigma:** Cultural and institutional stigma slows provider participation.

**Lack of Standards:** No clear protocols for psychotherapy dose, outcome metrics, or harm mitigation—raising medicolegal risks.





The background features a soft, abstract gradient of pink, blue, and orange. In the top left corner, there are stylized green stems with pink and yellow flowers, some with white starburst highlights. In the bottom right corner, there are stylized, colorful, wavy shapes resembling mushrooms or abstract plants in shades of orange, yellow, and green, also with white starburst highlights.

## Why It Matters

- Offers a real-world case study for other countries developing access pathways for psychedelic therapy.
- Highlights key implementation barriers: from red tape and training deficits to infrastructure and stigma.
- Shows how without reform, access will remain limited to those with privilege, defeating equity goals in mental healthcare.

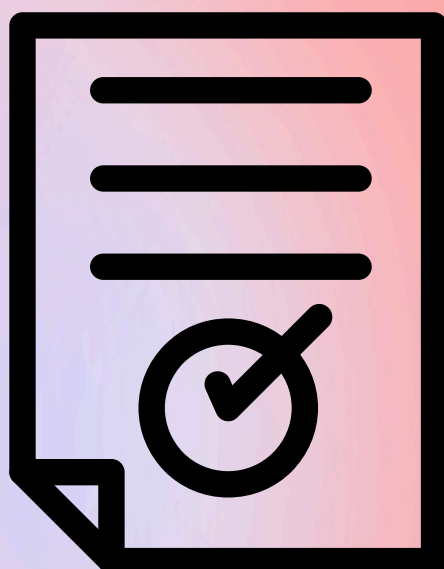


## Lessons & Future Directions

SAP reveals disconnect between research promise and clinical reality.

### Urgent need for:

- National training & certification standards
- Streamlined application processes
- Increased education for professionals and the public
- Clear medicolegal frameworks and outcome measures





# Study Limitations

Approval rate trends may reflect policy opacity rather than therapeutic inefficacy.







## Conclusions

The study provides rare insights into real-world psychedelic therapy but highlights systemic obstacles.

PAP shows potential but faces a fragmented and under-resourced clinical and regulatory environment.

Clearer regulatory guidelines, provider training, and standard-of-care frameworks are essential to scale access.





## Citation

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