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

By: Psychedelics Canada

List of Recommendations

• Recommendation 1: That the government provide funding in the amount of \$50 million over 5 years through the Canadian Institutes for Health Research (CIHR) for further study of psychedelic-assisted therapies for the treatment of mental and physical problems.



Body of Submission

Numerous landmark scientific articles demonstrate the efficacy and safety 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), Tobacco Use Disorder (TUD), Post-Traumatic Stress Disorder (PTSD), and Opioid Use Disorder (OUD). Results from most trials show psychedelic-assisted psychotherapy (PAP) can be more effective and faster than current treatments.¹

This year, the Canadian Institutes of Health Research (CIHR) announced *Operating Grant: Psilocybin-assisted Psychotherapy for Mental Health and Substance Use Disorders* to support phase 1 and 2 clinical trial research into the safety and efficacy of using psilocybin, in combination with a psychotherapy, to treat substance use and mental health disorders.

Our request for \$50 million over 5 years would allow further grants through the CIHR for the investigation by qualifying research institutions of psilocybin and additional psychedelic drugs, including but not limited to N,N-Dimethyltryptamine (DMT), 3,4-methylenedioxy-methamphetamine (MDMA), Lysergic acid diethylamide (LSD), lbogaine, and Ketamine as adjuncts to therapies for mental and physical health conditions.

To date, the majority of the clinical trials establishing efficacy and safety of classical psychedelic molecules—such as psilocybin or MDMA—have been funded by charitable donations. As these molecules are off-patent, there is limited likelihood the private sector will fund further research. However, the use of these molecules represents a unique opportunity to provide exceptional, cost-effective treatment to Canadians for a range of poorly-treated disorders. Psychedelics Canada's economic analysis indicates that the treatment of PTSD through MDMA-assisted psychotherapy alone may represent potential savings of \$3.8 billion in healthcare costs per year.² As such, it is crucial that government fills a research gap unlikely to be filled by the pharmaceutical industry through academic funding through the CIHR.

About Psychedelics Canada (PsyCan)

Psychedelics Canada (PsyCan), incorporated as the Psychedelics Businesses Association, is the not-for-profit trade association for the legal psychedelic medicine and therapy sector. We are researchers, healthcare providers, drug developers, and suppliers producing and working with psychedelic medicine. We are devoted to collective action and motivated by a belief in the promise of psychedelic molecules for therapeutic treatments.

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

²Psychedelics Canada Sector Report. Pg 21. Ran Moaz. Psychedelics Canada. September 25, 2022. www.psychedelicscanada.org/sectorreport.

Published Scientific Articles of Psychedelic Research

Chronic pain and psychedelics: a review and proposed mechanism of action. Joel P Castellanos et al. Reg Anesth Pain Med 2020; 0:1–9.

Classic and non-classic psychedelics for substance use disorder: A review of their historic, past and current research. Fúlvio Rieli Mendes et al. Addiction Neuroscience 3 (2022) 100025.

Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder. A Randomized Clinical Trial. Alan K. Davis et al. JAMA Psychiatry. 2021;78(5):481-489.

Exploratory Controlled Study of the Migraine-Suppressing Effects of Psilocybin. Emmanuelle A. D. Schindler et al. Neurotherapeutics (2021) 18: 534-543.

Exploring ayahuasca-assisted therapy for addiction: A qualitative analysis of preliminary findings among an Indigenous community in Canada. Elena Argenta et al. Drug and Alcohol Review (2019).

Ketamine Assisted Psychotherapy (KAP): Patient Demographics, Clinical Data and Outcomes in Three Large Practices Administering Ketamine with Psychotherapy. Jennifer Dore et al. Journal of Psychoactive Drugs. 2019, Vol. 51. No. 2, 189–198.

Ketamine for the treatment of mental health and substance use disorders: comprehensive systematic review. Zach Walsh et al. BJPsych Open (2022) 8, e19, 1–12.

Long-term Follow-up of Psilocybin-facilitated Smoking Cessation. Matthew W. Johnson et al. Am J Drug Alcohol Abuse. 2017 January; 43(1): 55–60.

Lysergic acid diethylamide-assisted therapy in patients with anxiety with and without a life-threatening illness A randomized, double-blind, placebo-controlled Phase II study. Friederike Holze et al. Biological Psychiatry (2022).

Meta-analysis - LSD for alcoholism. Goldberg, S. B. et al (2020). Psychiatry Research, 284, 112749.

Meta-analysis of placebo-controlled trials of psychedelic-assisted therapy. Luoma, J. B., et al. 2020. Journal of Psychoactive Drugs, 52(4), 289-299.

Psilocybin-assisted treatment for alcohol dependence: a proof-of-concept study. Michael Bogenschutz, et al. January 2015. Journal of Psychopharmacology 29(3).

Psilocybin microdosers demonstrate greater observed improvements in mood and mental health at one month relative to non-microdosing controls. Joseph M. Rootman et al. Scientific Reports Volume 12, 11091 (2022).

Percentage of Heavy Drinking Days Following Psilocybin-Assisted Psychotherapy vs Placebo in the Treatment of Adult Patients with Alcohol Use Disorder: A Randomized Clinical Trial. Michael P Bogenschutz et al. JAMA Psychiatry. 2022 Oct 1;79 (10): 953-962.

Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. Roland R Griffiths et al. (2016). Journal of Psychopharmacology 2016, Vol. 30(12) 1181–1197.

Psilocybin with psychological support for treatment-resistant depression: six-month follow- up. R. L. Carhart-Harris et al. (2018). Psychopharmacology (2018) 235:399–408.

Reviewing the Potential of Psychedelics for the Treatment of PTSD. Erwin Krediet et al. International Journal of Neuropsychopharmacology (2020) 23(6): 384-400.

Three Naturally-Occurring Psychedelics and Their Significance in the Treatment of Mental Health Disorders. Nataliya Vorobyeva et al. Frontiers in Pharmacology. June 2022 | Volume 13 | Article 927984.