

February 10, 2021

BY EMAIL

Office of Legislative and Regulatory Affairs
Controlled Substances Directorate
Health Canada
Email: hc.csd.regulatory.policy-politique.reglementaire.dsc.sc@canada.ca

Dear Sirs,

RE: Proposal to restore potential access to restricted drugs through Special Access Program

Cannabis and Psychedelics Law Group LLP support making restricted drugs available under the Special Access Program (SAP). The SAP was designed as a mechanism to allow health care professionals to request drugs not ordinarily for sale in Canada for emergency access. SAP guidance documents state that a medical emergency refers to conditions that are serious or life threatening. If the SAP is granted, the Minister issues a letter of authorization authorizing the sale by the manufacturer directly to the health care professional.

Currently, subsections C.08010(3) and C.08011.1(2) in Part C of the *Food and Drug Regulations* prohibit access to restricted drugs. Restricted drugs include psychedelic medicines such as psilocybin, MDMA, LSD, and DMT. The prohibition permits no wiggle room. No matter how severe the health situation or how compelling the arguments, restricted drugs cannot be sold or given for medicinal purposes. The prohibition makes no sense as restricted drugs have medicinal uses. There is a vast ocean 70 years deep of compelling science showing, to varying degrees, that these drugs are safe and efficacious for a range of health issues.

Psilocybin-assisted therapy has been found to be efficacious in producing rapid, large and sustained antidepressant effects in patients with major depressive disorder.¹ Patients with treatment-resistant depression experienced reduction in symptoms of depression and anxiety that continued months after being administered psilocybin. Psilocybin has been found to decrease symptoms of depression, anxiety and death anxiety, along with increases in quality of life, life meaning and optimism, with long-lasting and sustained effects for patients with cancer-related psychiatric distress. Psilocybin is promising in the treatment of tobacco and alcohol addictions.^{2,3} Psilocybin can facilitate the recall of

1. Davis, Alan K., Frederick S. Barrett, Darrick G. May, Mary P. Cosimano, Nathan D. Sepeda, Matthew W. Johnson, Patrick H. Finan, and Roland R. Griffiths. "Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder: A Randomized Clinical Trial." *JAMA Psychiatry (Chicago, Ill.)* (2020), <https://doi.org/10.1001/jamapsychiatry.2020.3285>

2. Johnson, Matthew W. and Roland R. Griffiths. "Potential Therapeutic Effects of Psilocybin." *Neurotherapeutics* 14, no. 3 (2017): 734-740.

3. Griffiths, Roland R., Matthew W. Johnson, Michael A. Carducci, Annie Umbricht, William A. Richards,

salient memories or to reverse negative cognitive biases by enhancing autobiographical recollection.⁴ It has also been found to acutely relieve symptoms of obsessive-compulsive disorder⁵, and aid in the treatment of cluster headaches.^{6,7}

MDMA can treat posttraumatic stress disorder (PTSD) because it allows patients to explore and address painful memories without feeling overwhelmed by the negative affect that usually accompanies such memories. MDMA can be a powerful tool in the treatment of alcohol use disorder^{8,9} and in the treatment of depression and anxiety disorders.¹⁰

LSD can be beneficial for patients with anxiety associated with severe illness, depression or addiction.^{11,12} LSD can be useful in psychotherapy because of the effects on emotional processing and social behavior. LSD produces feelings of happiness, trust, closeness to others, and to enhance explicit and implicit emotional empathy. LSD enhances the desire to be with other people as well as increases prosocial behaviour.¹³

Ayahuasca/ DMT has shown promising results in the treatment of anxiety, depression, and substance dependence.^{14,15} Evidence suggests that Ayahuasca/ DMT is safe and can help treat depression.¹⁶

Brian D. Richards, Mary P. Cosimano, and Margaret A. Klinedinst. "Psilocybin Produces Substantial and Sustained Decreases in Depression and Anxiety in Patients with Life-Threatening Cancer: A Randomized Double-Blind Trial." *Journal of Psychopharmacology (Oxford)* 30, no. 12 (2016): 1181-1197.

4. Carhart-Harris, R. L., R. Leech, T. M. Williams, D. Erritzoe, N. Abbasi, T. Bargiotas, P. Hobden, et al. "Implications for Psychedelic-Assisted Psychotherapy: Functional Magnetic Resonance Imaging Study with Psilocybin." *British Journal of Psychiatry* 200, no. 3 (2012): 238-244.

5. Moreno, Francisco A., Christopher B. Wiegand, E. Keolani Taitano, and Pedro L. Delgado. "Safety, Tolerability, and Efficacy of Psilocybin in 9 Patients with Obsessive-Compulsive Disorder." *The Journal of Clinical Psychiatry* 67, no. 11 (2006): 1735-1740.

6. Sempere, A. P., L. Berenguer-Ruiz, and F. Almazán. "Chronic Cluster Headache: Response to Psilocybin." *Revista De Neurología* 43, no. 9 (2006): 571.

7. Sewell, R. Andrew, John H. Halpern, and Jr Pope Harrison G. "Response of Cluster Headache to Psilocybin and LSD." *Neurology* 66, no. 12 (2006): 1920-1922.

8. Sessa, Ben. "MDMA and PTSD Treatment: "PTSD: From Novel Pathophysiology to Innovative Therapeutics"." *Neuroscience Letters* 649, (2017): 176-180.

9. Sessa, Ben. "Why MDMA Therapy for Alcohol use Disorder? and Why Now?" *Neuropharmacology* 142, (2018): 83-88.

10. Yazar-Klosinski, BB and MC Mithoefer. "Potential Psychiatric Uses for MDMA." *Clinical Pharmacology and Therapeutics* 101, no. 2 (2017): 194-196.

11. Gasser, Peter, Dominique Holstein, Yvonne Michel, Rick Doblin, Berra Yazar-Klosinski, Torsten Passie, and Rudolf Brenneisen. "Safety and Efficacy of Lysergic Acid Diethylamide-Assisted Psychotherapy for Anxiety Associated with Life-Threatening Diseases." *The Journal of Nervous and Mental Disease* 202, no. 7 (2014): 513-520.

12. Liechti, Matthias E.. "Modern Clinical Research on LSD." *Neuropsychopharmacology (New York, N.Y.)* 42, no. 11 (2017): 2114-2127.

13. Dolder, Patrick C., Yasmin Schmid, Felix Müller, Stefan Borgwardt, and Matthias E. Liechti. "LSD Acutely Impairs Fear Recognition and Enhances Emotional Empathy and Sociality." *Neuropsychopharmacology (New York, N.Y.)* 41, no. 11 (2016): 2638-2646.

14. Ribeiro Barbosa, Paulo Cesar, Joel Sales Giglio, and Paulo Dalgalarondo. "Altered States of Consciousness and Short-Term Psychological After-Effects Induced by the First Time Ritual use of Ayahuasca in an Urban Context in Brazil: Ayahuasca use in Cross-Cultural Perspective." *Journal of Psychoactive Drugs* 37, no. 2 (2005): 193-201.

15. Rodrigues, Alexandra VSL, Francisco Jcg Almeida, and Maria A. Vieira-Coelho. "Dimethyltryptamine: Endogenous Role and Therapeutic Potential." *Journal of Psychoactive Drugs* 51, no. 4 (2019): 299-310.

16. Palhano-Fontes, Fernanda, Dayanna Barreto, Heloisa Onias, Katia C. Andrade, Morgana M. Novaes, Jessica A. Pessoa, Sergio A. Mota-Rolim, et al. "Rapid Antidepressant Effects of the Psychedelic Ayahuasca in Treatment-Resistant Depression: A Randomized Placebo-Controlled Trial." *Psychological Medicine* 49, no. 4 (2019):

Psychedelics can be useful tools for the treatment of anxiety, depression, and mood disorders, particularly in treatment-resistant patients, as well as for the treatment of addictions.¹⁷ All conditions that are ravaging Canada as well as the rest of the world. Psychedelics also have been found to have anti-inflammatory potential.¹⁸ In the U.S., MDMA and psilocybin therapy have been granted breakthrough therapy status. All of this recent research is supplemented by a long strong research track record that goes back in western culture to the early 1950s and in non-western culture thousands of years. These are not new drugs. If not for all the irrational prohibitions, we would be a lot further along this road.

The federal government has been taking some positive steps. The Minister of Health has recently issued section 56 exemptions to the *Controlled Drugs and Substances Act* possession of psilocybin prohibition. The exemptions do not provide for a supply. The change to the SAP could help remedy that. Also, in August 2020, the Public Prosecution Service of Canada issued new guidelines for the prosecution of simple possession of controlled substances. The new guidelines provide that prosecutors should resort to the prosecution of simple possession only in the most serious cases. The prosecution of simple possession of drugs should never have happened, but better late than never. As well, of course, cannabis was legalized in October 2018.

This proposed change to the SAP is a further step in the right direction which will be met with near unanimous approval. It is good, but it is not enough. The SAP will fail patients. This is not an insult to those who administer the SAP. The SAP is simply ill-suited to the task. The decision as to whether to use psilocybin, MDMA, LSD, or DMT for medicinal purposes should be the patient's made in consultation with a doctor. The decision is a medical decision, not an administrative one. The considerations should be the health of the patient and the risks the patient is prepared to take. The decision must not involve administrative discretion.

Research has found the SAP to be value-laden in its decisions.¹⁹ Psychedelics have for many years faced research hurdles and unjust prohibitions born of senseless prejudice against psychoactive substances. The SAP is supposed to be for drugs in which there is inadequate evidence to permit the sale of the drug. And yet, the SAP requires data, but how much is unclear. In addition, effective medication sometimes takes longer to get to market because of business decisions made by manufacturers. The fact that deep-pocketed big pharma does not get behind a drug does not mean that the drug is not effective and that patients suffering terribly must be denied desired medicine.

Psychedelics, with their potential to do wonders after limited doses, may not be the most

655-663.

17. Dos Santos, Rafael G., Flávia L. Osório, José Alexandre S. Crippa, Jordi Riba, Antônio W. Zuardi, and Jaime E. C. Hallak. "Anti-depressive, Anxiolytic, and Anti-addictive Effects of Ayahuasca, Psilocybin and Lysergic Acid Diethylamide (LSD): A Systematic Review of Clinical Trials Published in the Last 25 Years." *Therapeutical Advances in Psychopharmacology* 6, no. 3 (June 2016): 196-213.

18. Nichols, DE, MW Johnson, and CD Nichols. "Psychedelics as Medicines: An Emerging New Paradigm." *Clinical Pharmacology and Therapeutics* 101, no. 2 (2017): 209-219.

19 Christie, Timothy K.S., Harris, Marianne, Montaner, Julio S.G. "Special Access Denied: A Case Study of Health Canada's Special Access Program." *Healthcare Policy* Vol. 2, No. 2, 2006.

lucrative drugs in the pharmacopeia. That should not drive the analysis. As has been pointed out by medical ethicists,

Our allegiance to evidence-based treatment should not be used as an excuse to justify excluding groups of patients from accessing treatment simply because research has not been done on them. A common mistake when assessing evidence is to assume that ‘no evidence of effect’ is equal to evidence of no effect. However, as Hartung et al. argued in 1983, the absence of evidence is not evidence of absence”. In the absence of evidence, a value judgment has to be made about whether to grant or deny access to treatment. Simply put when decisions cannot be based on evidence, they must be based on values.²⁰

Patients will suffer if access to psychedelics is based on value-laden decision making. The *Food and Drug Regulations* provide that the Minister “may” issue a letter of authorization under the SAP. In other words, even if the test is met the Minister can still refuse applicants. Recourse from an SAP denial is non-existent. A long, expensive and uncertain judicial review to Federal Court would be the appeal equivalent in which a lawyer would be required. That is not practical for those of modest means and in vulnerable health. Even if one had the resources, it is a tough review because there is no standard compelling the Minister to do anything. How can one say the Minister made a mistake when the Minister is not obliged to do anything? The SAP needs to better articulate the rules.

An approach that empowers the patient and the patient’s doctor would be not just more humane, it would also be more in line with the *Charter of Rights and Freedoms* (the *Charter*). Section 7 of the *Charter* protects the right to liberty and security of the person and not to be deprived thereof except in accordance with the principles of fundamental justice. Liberty protects the rights of Canadians to make fundamental personal choices free from state interference.²¹ The liberty right entitles Canadians to direct the course of his own medical care.²² The security of the person right protects Canadians’ personal autonomy in matters concerning physical or psychological integrity.²³ That includes health decisions.

Cannabis and Psychedelics Law Group LLP applaud the government for considering this positive change in the law. However, the SAP is not answer. The decision as to whether to use psychedelic medicine does not lend itself to administrative discretion. The decision must be made by patient and doctor.

20 Christie, Timothy, Jiwani, Bashir, Asrat, Getnet, Montessori, Valentina, Mathias, Richard, Montaner, Julio. “Ethical and scientific issues surrounding solid organ transplantation in HIV-positive patients: Absence of evidence is not evidence of absence.” *Can J Infect Dis Med Microbiol* Vol 17 No 1 January/February 2006.

21 *Carter v. Canada (Attorney General)*, 2015 SCC 5, at para. 64.

22 *Carter, supra*, at para. 67; *Manitoba v. C. (A.)*, 2009 SCC 30, at para. 40.

23 *Carter, supra*, at para. 64; *New Brunswick (Minister of Health & Community Services) v. G. (J.)*, [1999] 3 S.C.R. 46, at para. 58.

Yours sincerely,



Paul Lewin



CANNABIS AND PSYCHEDELICS
LAW GROUP LLP