Reopening the doors of perception: The psychedelics renaissance in Canada

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While cannabis takes a breather from the capital markets roller coaster ride that has characterized that sector lately, psychedelics are in the news lately – and all the rage in the capital markets. Junior pharmaceutical companies, specialized clinics and Caribbean retreats are common water-cooler topics of conversation these days among capital markets investors and observers alike. To be sure, momentum is building and public perception is changing in Canada and in some parts of the United States toward reducing barriers to access for psychedelics. Low enforcement priorities in Denver, Oakland and Santa Cruz, as well as Oregon's proposed laws to regulate cultivation, manufacture and sale of psilocybin products for medical purposes, broadens the discussion. Today's momentum has been a long time coming – particularly as a viable new option for mental health treatment.

Psychedelics, entheogens, entactogens and dissociative anesthetics are a broad group of substances that are intensely psychoactive, with effects including visual and other illusions, mystical-type experiences, synesthesia, intensified emotional states and other disorienting effects. Duration of these effects may range from 15 minutes or less to more than 24 hours. The terms for these compounds and the plants or fungi they are sourced from vary depending on the perspective and context. For simplicity, we use the term familiar to most – psychedelics – as a blanket term for psychedelics, entheogens, entactogens and dissociative anesthetics.

Prohibition, regulation and sale

Psychedelics are not illegal. That said, many psychedelics are scheduled in the *Controlled Drugs and Substances Act* (the CDSA), making them controlled substances and unless otherwise authorized, possession and manufacture of any controlled substance is prohibited. Most psychedelics that are controlled substances are within a certain class of controlled substances called "restricted drugs". Investigators for clinical trials, preclinical studies and other researchers may possess restricted drugs through exemptions issued under the CDSA. Authorization to manufacture, compound, package and otherwise work with restricted drugs is available through a dealer's licence issued under the *Food and Drug Regulations* (the FDR).

Like any drug substance, a drug product including a psychedelic substance as an active pharmaceutical ingredient (API) is saleable under the FDR once a drug identification number (DIN) is issued by Health Canada for use of the drug product in association with a given therapeutic indication. Clinical evidence establishing safety of a drug product and efficacy for treating a given condition is required for Health Canada to issue a DIN for the drug product. An MDMA drug product is on track to receive a DIN for use in treatment of post-traumatic stress disorder (PTSD) and the equivalent regulatory approval in the United States within the next two to four years. A psilocybin drug product for treatment-resistant depression appears to be close behind.

Psychedelics and mental health

Administration and application of psychedelic drugs diverges from previous approaches to the use of medication for treatment of mental health disorders. This point of divergence changes the economics of cost recovery for clinical trial expenses after being issued a DIN. Drug products traditionally used in treatment of mental health conditions are taken daily and unsupervised at dosage ranges intended to suppress symptoms of mental illness and to minimize overtly psychoactive effects. In contrast, in clinical trials MDMA and psilocybin are typically administered a small number of times at strongly psychoactive flood doses in a supervised therapy setting. Similar approaches will be followed in applications using flood doses of LSD, and for use of MDMA and psilocybin for other therapeutic indications. Clinics that currently administer racemic ketamine off-label for treatment of depression follow a similar model.[1]

The long duration of the effects resulting from a flood dose of most psychedelics increases the time required from therapists, often in specialized clinic settings designed to maximize the benefits of the psychoactive effects of psychedelics. Compared with previous approaches to management of mental health conditions, psychedelic assisted therapy uses a lower amount of drug substance and involves a greater amount of time spent with therapists. As a result, a much greater portion of the value chain for administration of a psychedelic drug product is captured by therapists relative to the manufacturer of the drug product. “Microdosing” psychedelics, which is generally defined as taking about five to ten per cent the dosage of a flood dose, presents a potential commercialization pathway for a drug product to be taken regularly and without supervision.

Mental health is a serious problem globally. This problem is likely exacerbated by the current global pandemic. Based on scientific evidence, psychedelics are likely to play a significant role in correcting this problem. Particularly in the last ten years or so, there has been growing attention on psychedelics and their potential therapeutic applications. World-class academic institutions and sophisticated, well-financed public companies are studying the potential benefits of LSD, psilocybin, MDMA, ibogaine and DMT for indications including end of life depression, treatment resistant depression, PTSD, eating disorders, Alzheimer’s disease, substance use disorder and others. Commercialization efforts are underway and we can expect to see MDMA, psilocybin and potentially other psychedelics used as APIs in drug products holding a DIN.

Psychedelics are not cannabis

While it is natural to draw a comparison to cannabis, psychedelics are not "the next cannabis." Cannabis products are a commodity-based and highly regulated category of consumer packaged goods (CPG). Cannabis has a well-defined adult use market that was built on a multi-participant commercial medical cannabis industry. Cannabis is also commonly used on a daily basis. Robust consumer demand for cannabis products supports an industry including cultivation, processing, retail sale and all the "picks and shovels" needed to maintain consumer access to cannabis products.

In contrast to cannabis, there is no psychedelics industry – at least not today. Rather, psychedelics are a disruptor for health care delivery and pharmaceuticals. Cannabis is a single heterogeneous commodity in high demand for manufacture of CPGs. In contrast, psychedelics are a diverse group of chemicals that vary widely in their effects.[2] Also contrasting with a commodity-based CPG industry, psychedelics for use in a therapeutic context are typically used sparingly and can currently be commercialized only as drug products regulated under the FDR.

There is plenty of noise circulating around psychedelics. While drug products holding a DIN and including a psychedelic substance API are likely to disrupt how therapy is delivered, there is no medical access program in Canada similar to the *Marihuana for Medical Purposes Regulations* for any psychedelics and there may never be. We believe that the market, and the strengths that distinguish the leaders, will be very different for psychedelics compared with cannabis.

Psychedelics practice at BLG

Borden Ladner Gervais LLP's Cannabis Industry Focus Group has a proven track record of helping companies in the cannabis ecosystem achieve their goals. We have leading regulatory, capital markets, intellectual property, corporate and commercial subject matter experts in the cannabis industry. Our focus group is national in scope and includes professionals across many disciplines.

We work with leading processors, retailers, technology companies, cultivators and others in the cannabis industry. We carry significant technical expertise alongside our legal experience. We understand the cannabis industry and are passionate about helping the legislative purpose of the *Cannabis Act* succeed.

Psychedelics are not cannabis. That said, overlapping legal and technical expertise positions our Cannabis Industry Focus Group for success in supporting clients working with psychedelics. BLG's entrepreneurial and leading approach to legal practice is a perfect match for working with clients operating in the psychedelics space. Our Cannabis Industry Focus Group has developed a strong practice advising clients focused on innovation, finance, drug substance and precursor manufacture, clinical work and data analysis in relation to psychedelics. We are also representing clients on key pro bono efforts to broaden access to psychedelics for medical purposes.

If you are considering directly entering, investing in, partnering into or otherwise pursuing a business plan that includes psychedelics, we would be pleased to speak with you to assess how our expertise can benefit your project.

[1] Spravato® (esketamine) is a drug product initially approved in Canada on May 19, 2020 that includes a nasal spray formulation of esketamine for treatment of depression. As indicated in the Spravato® product monograph, and analogously to off-label administration of racemic ketamine by health care practitioners to patients suffering from depression, self-administration of the Spravato® product by patients suffering from depression is intended to be completed only under the direct supervision of a healthcare professional with post-administration monitoring.

[2] Examples include LSD, psilocybin, MDMA, DMT, harmaline, salvinorin A, mescaline, 2C-B and other 2,5 substituted phenethylamines, DOM and other ring-substituted amphetamines, ketamine, mitragynine, ibogaine and many others.

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