# Canadian Government Agency Removes Barrier for Psilocybin Therapy

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PALM BEACH, Fla. , Dec. 16, 2020 /PRNewswire/ -- Health Canada , in a recent "breakthrough Exemption" has quietly expanded (https://thetyee.ca/News/2020/12/10/Health-Canada-Removes-Barrier-Psilocybin/) its list of who can legally possess and consume psilocybin-containing mushrooms by granting 16 health-care professionals the same exemptions it gave more than a dozen patients with terminal and mental illnesses, according to TheraPsil, a Victoria non-profit that has been behind the struggle to treat a list of mental health issues, including debilitating depression, PTSD and even terminal cancer patients. Psilocybin is currently being studied for its potential to treat various conditions such as anxiety, depression, obsessive compulsive disorder and problematic drug use. It is important to note that studies involving the use of Psilocybin require administration of the purified active ingredient in clinically supervised settings. As of right now, there are no approved therapeutic products containing Psilocybin in Canada. Active companies in news today include : **Pure Extracts Technologies Corp.** (CNSX:PULL.CN), **Mydecine Innovations Group** (CNSX:MYCO.CN), **Revive Therapeutics Ltd.** (OTCPK:RVVTF) (CNSX:RVV.CN), **Numinus Wellness Inc.** (OTCPK:LKYSF) (TSXV:NUMI.VN), **Entheon Biomedical Corp.** (OTCPK:ENTBF) (CNSX:ENBI.CN).

To legally possess and conduct activities with controlled substances in Canada , companies and research organizations must first obtain a controlled substances Dealer's License (or a Section 56 exemption for researchers (physicians, veterinarians and other researchers affiliated to universities and private industry) requiring a controlled substance for research purposes which include in vitro utilization, administration to

packaging, sale, sending, transportation, delivery, laboratory analysis, research & development, clinical studies, import/export or distribution under special access program only). Controlled substances can only be imported or exported if the shipment is authorized by a permit issued by Health Canada. Only a holder of a valid controlled substances Dealer's License is eligible to apply for an import/export permit. Health Canada's proposed intent to revise the Special Access Programme (SAP) and related regulations to permit certain authorized uses of psilocybin-assisted psychotherapeutic treatments. The intended SAP revision, announced on December 11th , could lead to important new medical applications, particularly in the complex and growing mental health sector.

**Pure Extracts Technologies Corp.** (CNSX:PULL.CN) (PULL.CNX) **BREAKING NEWS - Pure Extracts Commences Build-Out of Facility in Preparation for Mushroom Extraction and Dealers License -** Pure Extracts Technologies Corp. ("Pure Extracts" or the "Company"), a plant-based extraction company, is pleased to announce that it has begun to build-out the 4 $^{th}$ unit in its facility for the extraction of mushrooms and to commence research and development of psilocybin under a Dealers License.

The Company is preparing an application to Health Canada for a Dealers License under the Controlled Drugs and Substances Act (CDSA), which provides, among other things, the framework for legal access to controlled substances, and the control and regulation of production, distribution and sale of psilocybin

Under this framework, a company is required to obtain a license issued by Health Canada in order to conduct various activities with controlled substances. License holders are responsible for compliance with the CDSA and its Regulations as well as compliance with other applicable federal, provincial and territorial legislation and municipal by-laws. The issued license dictates activities, conditions, and restrictions for the license holder depending on license permissions.

A Dealer's License could allow for the following activities:

- Procurement of controlled substances, including by import, synthesis, propagation, cultivation and harvesting of psychedelic mushrooms for psilocybin extraction
- Research and manufacture of controlled substances such as psilocybin and psilocin
- Business to business sale of controlled substances, including by export
- Sale of controlled substance via pharmacies

Pure Extracts CEO, Ben Nikolaevsky , remarked, "As a plant-based extractor bringing functional mushroom products to market in Q1 2021, we are very excited to be building-out our facility for our move into the controlled substances world of psychedelics. It's great to have space adjacent to our cutting-edge facility which is built to Health Canada standards and to know that this space will also have the same high standards of construction that Pure Extracts prides itself on."

Having the ability to do extraction research and development into psychedelic compounds such as psilocybin and psilocin will prepare Pure Extracts to work with partners such as medical doctors, pharmaceutical company and pharmacies as clinical trials lead to the legalization of psychedelics and the advancement of micro-dosing in the near future. **Read more news for Pure Extracts by visiting:** https://www.financialnewsmedia.com/news-pull/ (https://www.financialnewsmedia.com/news-pull/)

In other industry news of note:

**Mydecine Innovations Group** (CNSX:MYCO.CN) (MYCO.CNQ), an emerging biopharma and life sciences company committed to the research, development, and acceptance of alternative nature-sourced therapeutic medicine for mainstream use, recently announced (https://finance.yahoo.com/news/mydecine-innovations-group-engages-propharma-123000101.html) that it has partnered with ProPharma Group, the leading provider of regulatory and compliance services to the pharmaceutical, biotech, and medical device industries. As part of the agreement, ProPharma Group will provide regulatory advisement as the company seeks approval from the Food and Drug Administration (FDA) for its drug development platform as well as the Company's various stage clinical trials.

"ProPharma Group is a globally recognized firm with a strong track record of working with life sciences and biopharma companies to ensure full compliance with all FDA regulations, including all necessary steps for eventual global federal approvals," said Josh Bartch , CEO and Co-Founder of Mydecine. "Mydecine currently has a jam-packed clinical trial calendar with plans to expand it to include additional various phase trials throughout the globe. Additionally, Mydecine has built a strong IP position in the psychedelics space. As we build upon our drug development platform, ProPharma Group will be a key partner for us as we explore the most efficient regulatory pathway in our mission to bring innovative treatments to the forefront for people suffering from mental health issues like PTSD and addiction."

**Revive Therapeutics Ltd.** (OTCPK:RVVTF) (CNSX:RVV.CN) (RVV.CNQ), a specialty life sciences company focused on the research and development of therapeutics for medical needs and rare disorders, recently provided (https://finance.yahoo.com/news/revive-therapeutics-provides-oral-thin-141000208.html) an update on its oral thin-film delivery system with psilocybin being developed under a research partnership agreement with Reed Research Group out of the University of Wisconsin-Madison .

Following several months of prototyping on a wide range of dosage forms, the Company has completed an oral thin-film strip product with psilocybin with dosage forms ranging between 1 mg and 20 mg and demonstrating its versatility through physio-chemical characterization (e.g. tensile strength of films) of bio comparable tannin-chitosan composite materials, dissolution and disintegration testing, and rate of psilocybin release from composites. Currently technical and scientific data is being processed and finalized.

**Numinus Wellness Inc.** (OTCPK:LKYSF) (TSXV:NUMI.VN), a company creating an ecosystem of health solutions centered around developing and supporting the safe, evidence-based, accessible use of psychedelic-assisted psychotherapies (PAP), recently announced (https://finance.yahoo.com/news/iiroc-trading-halt-harv-200800830.html) the acquisition of Montreal-based Mindspace Psychology Services Inc (DBA Mindspace Wellbeing) a leader and pioneer in psychedelic programming. The agreement brings together the capabilities of two leading Canadian organizations to develop and scale delivery of evidence-based psychedelic-assisted psychotherapy to provide the highest quality patient outcomes.

"Adding Mindspace to the Numinus platform will provide strong synergies for both companies," said Dr. Devon Christie, Medical Director at Numinus and a MAPS-trained therapist for the delivery of MDMA-assisted psychotherapy. "The companies have similar values and complementary strengths, which make this a strong corporate and cultural fit. We are also proud to grow our presence nationally through this announcement."

**Entheon Biomedical Corp.** (OTCPK:ENTBF) (CNSX:ENBI.CN) (ENBI.CNQ) , a biotechnology company focused on developing psychedelic medicines to treat addiction, recently announced (https://finance.yahoo.com/news/entheon-biomedical-announces-dmt-drug-133000262.html) it has entered into a drug-supply agreement (the "Agreement") with Psygen Labs Inc. ("Psygen"). Under the terms of the Agreement, Psygen will supply Entheon with non-GMP and GMP (good manufacturing practice) quality N,N-dimethyltryptamine drug substances ("DMT") for upcoming formulation, preclinical, clinical, and post-approval commercialization phases under the European Medicines Agency (EMA) regulatory framework. On November 27, 2020 , Psygen successfully completed the production of a non-GMP DMT research batch for delivery to the Company's Contract Research Organization, CHDR's partner pharmacy. The non-GMP DMT research batch will be shipped to CHDR upon receipt of Psygen's export permit from the Health Canada Office of Controlled Substances. This export permit will be applied for following the successful receipt of CHDR's import permit, which has been applied for, and the granting of which is anticipated by the end of December.

The Agreement entered into on August 21, 2020 provides Entheon with access to a consistent DMT drug material for preliminary formulation, stability and testing required prior to its forthcoming human clinical trial, scheduled to begin in Q4 2021 at The Centre for Human Drug Research (CHDR) in the Netherlands .

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