

Numinus Wellness Commends Health Canada on Special Access Programme Amendments to Restore Potential Access to Psychedelic Medicines

Policy amendment allows practitioners to request access to psychedelic drugs for patients with serious or life-threatening conditions on a case-by-case basis

VANCOUVER, BC, Dec. 22, 2021 /CNW/ - Numinus Wellness Inc. ("Numinus" or the "Company") (TSX: NUMI), a leader in psychedelics-focused mental healthcare, commends Health Canada's leadership for amending the Special Access Programme (SAP) to allow physicians to request patient access to psychedelic treatments, such as MDMA- and psilocybin-assisted therapy, for serious treatment-resistant or life-threatening conditions on a case-by-case basis. The amendment has the potential to positively affect the lives of people experiencing serious mental health conditions when other therapies have failed, are unsuitable or are unavailable in Canada.

"Amending the SAP and righting a historical wrong based on stigma highlights Canada's commitment to making psychedelic-assisted therapies a possibility for the many Canadians who struggle with mental wellness," said Payton Nyquvest, Founder and CEO, Numinus. "While we believe this is only the beginning of greater change to come, it signifies an important step towards creating expanded safe access to treatment and care in the mental health sector through psychedelic medicine. I am proud of our team who have had a longstanding role in advocating for this reform."

Health Canada's amendment recognizes a growing body of research, including the work that Numinus' clinical and research teams are completing, that has consistently shown the efficacy of psychedelic-assisted psychotherapy to treat a broad range of mental health conditions that are currently extremely difficult to treat with conventional therapies. According to Health Canada, access will be provided when there is sufficient data to support the safety and efficacy of the drug for the specific condition of the patient and will be available once the regulations come into force when the amendment is published in the Canada Gazette, which is anticipated on January 5th, 2022.

"Revising the SAP to allow for a case-by-case consideration of the suitability of psychedelic-assisted psychotherapy is a critical first step towards patients having access to these potentially transformative, safe and effective treatments when other treatments have failed," said Dr. Lindsay Farrell, Vice President of Indigenous Initiatives and Reconciliation, Numinus. "Nevertheless, new pathways ensuring equitable access to psychedelic-assisted therapies for racialized, marginalized, underserved populations and Indigenous Peoples are also urgently needed, especially in the context of sacred plants that have been used in cultural practices by Indigenous Peoples since *Time Immemorial*. We encourage the federal government to create regulations that acknowledge and honour the traditional use of certain sacred plants and create pathways for safe and equitable access."

Added Dr. Evan Wood, Chief Medical Officer, Numinus: "We applaud Health Canada and hope this is the first in a series of regulatory reforms where the federal government can provide leadership with the best interests of Canadians in mind. We know that, with all currently illegal drugs, doing nothing only creates public and patient safety concerns that can best be addressed by thoughtful regulatory approaches."

The Special Access Programme (SAP)

The SAP was designed to allow people access to new, potentially life-saving medications before they are formally approved for routine use in healthcare.

Historically, psychedelic medications have been ineligible for Special Access Programme applications. The regulatory amendment, which is expected to come into force on January 5th, 2022, will enable Canadian physicians to apply for psychedelic therapies in a similar process as to how other investigational medications are accessed prior to formal drug approval.

A substantial body of research, including the completion of a growing number of randomized clinical trials, has demonstrated that psychedelic-assisted therapies using psilocybin and MDMA appear to be highly effective approaches for the treatment of a host of potentially life-threatening mental health conditions, including treatment-resistant depression, post-traumatic stress disorder (PTSD), substance use disorders, and severe anxiety associated with terminal diagnoses.

In addition to allowing ongoing access for research participants after a clinical trial is complete, the SAP enables physicians to apply for access on behalf of qualifying Canadians who have serious or life-threatening conditions.

Patients cannot apply to the SAP directly, and only licensed healthcare practitioners who are authorized under the laws of a province or territory to treat patients with a prescription drug may file requests through the SAP.

About Numinus

Numinus Wellness (TSX: NUMI) helps people to heal and be well through the development and delivery of innovative mental health care and access to safe, evidence-based psychedelic-assisted therapies. The Numinus model - including psychedelic production, research and clinic care - is at the forefront of a transformation aimed at healing rather than managing symptoms for depression, anxiety, trauma, pain and substance use. At Numinus, we are leading the integration of psychedelic-assisted therapies into mainstream clinical practice and building the foundation for a healthier society.

Learn more at www.numinus.com and follow us on [LinkedIn](#), [Facebook](#), [Twitter](#), and [Instagram](#).

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