Cassels

Update in the Psychedelics Space: Ensuring Compliance with Health Canada Framework

A. Chandimal Nicholas

06/17/2021

With the rise in interest in the potential medical and therapeutic benefits of psychedelics, it is important that persons involved in the psychedelics industry understand Health Canada's rules and regulations. Based on our review of public discourse regarding psychedelics, there appear number of common misconceptions about the rules governing the acquisition, sale, distribution, and use of psychedelic compounds such as psilocybin (i.e., the active ingredient found in magic mushrooms) in Canada. For example, many commentators have compared the current psychedelics business and regulatory landscape to the Canadian Cannabis industry, which is a comparison that is flawed for reasons that we explore here. As noted in our previous article, psychedelic substances are treated very differently under Canadian laws and the commercial opportunities available to those who wish to become involved in the industry differ significantly.

There are currently two streams in which psychedelics are being utilized in the Canadian regulatory landscape. The first stream revolves around research and development of psilocybin (and other psychedelics) for use in treating various diseases/disorders. To do this, a company requires an exemption under Section 56 of the *Controlled Drugs and Substances Act*[1](and if clinical trials are being conducted further regulatory approvals). The second stream relates to the manufacture of psilocybin and other similar controlled substances (e.g., psilocin) to be sold to persons conducting the research and development. The ability to manufacture these substances can be obtained by securing an authorized dealer's license from Health Canada which allows for certain activities to be conducted with specific compounds. The permitted activities will depend on the dealer's license for which one applies.

Any sale to the public or use as a medical treatment of controlled substances outside the current regulations would be of great concern to the regulators and law enforcement. For clarity, at present (and for the foreseeable future) neither a dealer's license or any other license or exemption currently available through Health Canada allows for public sale or distribution of any controlled substance, including for medical or therapeutic purposes or otherwise.

In response to the growing interest in psychedelics as well as the unauthorized uses of controlled substances pursuant to dealer's licenses Health Canada is taking steps to ensure that license holders abide by the restrictions on these substances. As an initial step, Health Canada has initiated a review of all holders of dealer's licenses that allow for the use and exploitation psilocybin. The review consists of Health Canada providing a series questions for the license holder to respond to in connection with their activities under their dealer's license. The scope and nature of the questions differ depending on the nature of the

license granted, but the following are common questions that are illustrative of the information that Health Canada is currently soliciting:

1. Please explain in detail what activities you are conducting with Psilocybin.
2. If you are conducting research with Psilocybin, please provide detailed information on the research you are conducting or intend to conduct.
3. Please provide a list who you are or are intending to sell or provide Psilocybin to.
4. Please provide specific details as to how you are producing the Psilocybin.
5. If you are producing a preparation or drug in dosage form (capsule, tablet, etc.) which contains Psilocybin, please provide details on the preparation(s) you are producing (quantity per capsule, tablet, etc.).
6. If you are cultivating the fungi, please provide details on the security measures of the cultivation location.
7. Please provide the details on the supplier of the starting material(s) to be used in the production.
8. If you are producing the raw material, please provide the total quantity of Psilocybin you have or are intending to produce in this calendar year.
9. If you are not producing Psilocybin, please provide the details on the supplier of the substance.

In responding to the questions posed by Health Canada, it is important that license holders (and persons relying on other exemptions) respond in a manner that make it clear that they understand and follow the framework in which they can legally operate in order to retain their license or exemption.

If you are unsure if you or your company is adequately meeting Health Canada standards, we recommend seeking legal advice to ensure your responses are appropriate and comply with the applicable regulations so that you may continue to operate. Our team would be happy to help.

Learn more about our experts in the regulatory space and how they can help.

---

[1] S.C., 1996, c. 19.

This publication is a general summary of the law. It does not replace legal advice tailored to your specific circumstances.