



Appendix to feedback on the proposed Drugs, Poisons and Controlled
Substances Amendment (Schedule 9 Poisons) Regulations
August 2022



MIND MEDICINE A U S T R A L I A

TO: The Secretariat
Medicines Rescheduling Unit
Therapeutic Goods Administration
Canberra
Australia

FROM: Thomas Hartle
151 Pezer Cres.
Saskatoon, SK
S7S 1J6
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Email: thomas@hartle.com

DATE: Feb 28, 2021

First, I would like to say thank you for the opportunity to speak about my patient experience with you. My name is Thomas Hartle, and I am a Canadian who has been dealing with stage 4 colon cancer for the past 5 years. I have undergone a significant number of different treatments and therapies as part of my condition. These therapies include medical procedures, naturopathic procedures, and several natural supplements. I am the first person in Canada to legally use psilocybin to treat the anxiety I have experienced as a result of my terminal cancer.

What we are considering here is not a discussion of the recreational use of a drug, which is a completely different matter from the use of any drug in a controlled clinical setting with medical supervision. I'm including here a copy of the section 56 exemption that was granted to me by the Minister of health and the Office of Controlled Substances here in Canada so that you have an idea of the restrictions that are placed on the usage of psilocybin that ensure that safety is a primary concern.

Some of you may be familiar with the kind of devastating physical effects that having stage 4 cancer can cause, but like so many things concerning mental illness, we often do not speak about the mental and emotional toll that cancer also imparts. We seem to be more comfortable talking about topics like death than we are to address issues like anxiety. Mental health is somehow a taboo subject that makes people feel they are somehow weak or ashamed to seek help. My cancer has put me in a position where I simply do not have time left to ignore things the way that more healthy people are able to. When you have a terminal illness, hearing talk about studies that may (or may not) produce any outcome in 3 or more years' time is the equivalent of saying that nothing will be done for the rest of your life. Nothing will improve for the rest of your life. You will not get any relief from the anxiety or depression for the rest of your life, so every minute that you have left will likely be one where you are suffering. With a hopeless prognosis like this, it isn't surprising to find that many opt for suicide instead of the extended suffering that a lack of options guarantees. My personal experience is that this suffering can be alleviated effectively and with almost no side effects or risk.



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For someone like myself, factors such as the small possibility for a negative reaction from a psychedelic such as psilocybin are trivial in the face of the absolute certainty that stage 4 cancer kills nearly everyone who has it, often within 18 months. Equally, as someone with a terminal diagnosis, I assure you that the possibility of experiencing some discomfort because of a "bad trip" is also almost laughable if you understand the level of daily discomfort cancer causes. This daily discomfort for me was greatly compounded by the anxiety I experienced over the uncertainty my life now has.

The most common question I am asked about my experience with psilocybin is usually concerning how a psychedelic substance could have any effect on something seemingly unrelated like anxiety. I can offer you the comparison of my experience between a traditional anti-depressant and psilocybin.

In a nutshell, the anti-depressant suppresses feelings for the duration that the drug is in effect. It removed the depths of negative feelings to some degree, but it also removed a proportionate amount of the peaks of happiness and wellbeing. Without the drug, everything returned to its original state with the same busy thoughts that are inherent to having anxiety and depression. The use of this drug is a lifetime commitment. For some, this is an acceptable option, but for me, it was not OK to trade the rest of my life with anxiety for the rest of my life feeling numb.

By comparison, the psilocybin gave me a different perspective on my circumstances. It did not only change the way I was feeling, but it also changed the way that I thought about what was happening to me. I have used psilocybin twice, and at this point, I don't feel any need to use it again. My results are typical, and as someone who has been extremely public about what most people would consider a personal matter, I have been approached by numerous people who have shared their experiences with me on the therapeutic use of this medicine. This perspective shift and the life changing result it has had for me is a theme that I have heard repeated by every patient I have spoken to. Every experience is different, and some are certainly challenging from an emotional point of view. We have anxiety because we are dealing with difficult things. Dealing with difficult things is not easy no matter what mode of treatment you take.

I will not try to tell you that this is somehow a cure all for mental illness. Of course, it isn't, and anyone who says so certainly does not understand how it works any more than someone who says that it has no medicinal value. Information on the toxicity of psilocybin is readily available, as are studies by highly reputable universities. There is a large body of research that is available from the 60s prior to the criminalization of the entire class of drugs. Many of the claims made against psilocybin such as its addictive potential are simply not supported by actual research. For myself, my doctors, and my government, this was sufficient to give me the opportunity to see if it would also work for me in the same way that it worked for 80% or people in the studies.

I am grateful that my government representatives were not only well informed, but also acted in a way that showed real human compassion. It would have been a simple matter for them to just say no and wait for me to die and no longer present a problem for them. Instead, they demonstrated that in medical matters, life changing medical decisions such as this are best left between a patient and their doctor. While the government in no way condones or promotes the use of psilocybin for any purpose, they had the decency to recognise that I am an informed and intelligent adult, capable of making choices about my treatment.



It is my hope that my positive treatment outcome, and the positive outcomes of others would be enough to convince you that the possibility of alleviating the suffering of the terminally ill is worth exploring. I would suggest that it could also be a mechanism to provide the research data that would show that this is in fact an effective treatment. Simply allow people who are terminally ill and who wish to use this treatment based on their own informed research to provide you with the evidence of their experience as recorded by their supervising medical practitioner. Allow them to use this medicine with protocols that have been established in other studies and treat that as your starting point in the development of protocols that reflect your own medical practices. If it does not deliver a result like I have experienced, they are no further behind than before they started. If they get even a fraction of the relief I have, you will give them at least the chance to be present with their loved ones instead their illness. There is nothing more precious to a family with a terminally ill member than quality time together.

Thank you for your consideration,

Thomas Hartle.



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Health
Canada

Santé
Canada

Address Locator 0300B
Ottawa ON K1A 0K9

2020-08-04

20-110568-868
HC6-53-140-57

Thomas Hartle
151 Pezer Cres
Saskatoon SK S7S 1J6

Dear Thomas Hartle,

Please find attached an exemption granted under the *Controlled Drugs and Substances Act* (CDSA) to possess, transport, destroy and consume psilocybin mushrooms. This exemption is being granted pursuant to subsection 56(1) of the CDSA and is valid for a period of one year unless it is revoked or replaced by another exemption. Although we had mentioned the possibility of requiring a licence in our correspondence to you on June 25, 2020, please note that there will be no need for this step to occur.

Please carefully review the exemption, including all the terms and conditions. In particular, please note that this exemption is only valid for your personal use of psilocybin mushrooms. Failure to comply with the terms and conditions of the exemption may result in your exemption being suspended or revoked.

You should be aware that there has been limited research into the safety of psilocybin for medical use. Because psilocybin is not an approved therapeutic substance, the availability of scientific evidence demonstrating the safety and efficacy of psilocybin is limited.

All of the potential health risks associated with psilocybin may not yet have been identified. It is therefore recommended that you continue to assess whether the potential benefits associated with the use of psilocybin continue to outweigh the risks.

This exemption is granted on the understanding that you and your supporting practitioner assume the risks associated with the use of psilocybin. In granting you this exemption, Health Canada does not guarantee that the use of psilocybin will not have some adverse effect on your health.

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Health Canada has not approved psilocybin as a drug under the Food and Drugs Act and the Food and Drug Regulations. Health Canada has not approved the main active ingredient of psilocybin, as a drug under the *Food and Drugs Act* and the *Food and Drug Regulations*. There are no products containing psilocybin approved as therapeutic drugs in Canada.

You are strongly encouraged to report any adverse reactions that may be related to the use of psilocybin (including adverse food and drug interactions) to Health Canada through MedEffect Canada. Information regarding the report of adverse reactions can be obtained on the MedEffect Canada website at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html> or by telephoning the Canada Vigilance Regional Office at 1-866-234-2345.

Health Canada is available to discuss the exemption and its terms and conditions with you at any time.

Sincerely,

Michelle Boudreau
Director General
Controlled Substances Directorate
Health Canada

Attachment



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Canada

Address Locator 0300B
Ottawa ON K1A 0K9

2020-08-04

20-110568-868
HC6-53-140-57

Thomas Hartle
151 Pezer Cres
Saskatoon SK S7S 1J6

Dear Thomas Hartle,

We have concluded our evaluation of the information that has been provided by you and Dr. Watler in support of your request for permission to possess and consume psilocybin mushrooms. Although, at this time, there is insufficient evidence to demonstrate the medical need for psilocybin, consideration has been given to the grave nature of your medical condition and that the potential benefits to be derived from your use of psilocybin outweigh the potential risks. Pursuant to subsection 56(1) of the *Controlled Drugs and Substances Act* (CDSA), and subject to the terms and conditions herein, you are hereby exempted from the application of the following provisions of the CDSA when possessing, transporting and consuming psilocybin mushrooms, herein referred to as “psilocybin”, for the purpose indicated in your request:

- Subsections 4(1), 5(1), 5(2) and section 7 of the CDSA

Scope of the Exemption

This authority is being exercised under subsection 56(1) of the CDSA. Subject to the terms and conditions set out herein, this exemption allows you to perform the following activities with respect to psilocybin:

- Destroy;
- Transport;
- Possess for the purpose indicated in your request; and
- Prepare and consume for personal use.

This exemption applies only to the activities referred to above with respect to the plant material that contains psilocybin, listed as item 12 of Schedule III to the CDSA and as item 9 in the Schedule to Part J of the FDR and does not apply to salts of psilocybin.

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Terms and Conditions

The exemption herein is only applicable if you comply with the following conditions:

1. This exemption applies exclusively for the purpose of the possession, transportation, destruction and consumption of psilocybin for your psilocybin-assisted psychotherapy;
2. The quantity of psilocybin in your possession cannot exceed 5 g at any given time;
3. Psilocybin consumed under this exemption may only be consumed by you under the supervision of a medical practitioner while undergoing psilocybin-assisted psychotherapy;
4. Psilocybin must be disposed of through an appropriate method that is in conformity with municipal, provincial and federal regulations and legislation. The method of destruction used must alter or denature psilocybin to such an extent that its use or future use is rendered impossible or improbable. You or your designated medical practitioner must make a record with the following information:
 - a. the quantity of any psilocybin to be destroyed;
 - b. the date of destruction;
 - c. the method of destruction; and
 - d. the reason for destruction.

Immediately following the destruction, you or your designated medical practitioner are required to sign and print your name on a statement indicating that the psilocybin destroyed has been altered or denatured to such an extent that its consumption has been rendered impossible or improbable.

You or your designated medical practitioner must retain all records with respect to the destruction of psilocybin for the validity period of this exemption. All records made regarding the destruction of psilocybin must be made available to the Minister or an inspector upon request.

Record-Keeping

5. You or your designated medical practitioner are required to record the following information with respect to your possession of psilocybin:
 - the date and quantity of any psilocybin received; and
 - the quantity of psilocybin consumed.

You or your designated medical practitioner must keep and retain records for the validity period of this exemption.

6. You must take any measures that are necessary to ensure the security of the psilocybin in your possession against loss or theft; and

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7. Any loss or theft of the psilocybin must be reported to the Compliance and Monitoring Division, OCS within 10 days of the discovery, by emailing hc.ocs.reporting-rapporter.bsc.sc@canada.ca.

Should it be necessary to change these terms and conditions, you will be informed in writing and a reason for the change will be provided.

Suspension without notice

A suspension of this exemption without prior notice may be ordered if the Minister deems that such a suspension is necessary to protect public health, safety or security.

Revocation

This exemption may be revoked if you contravene any of the terms and conditions set out in this document (please note that such a contravention may, in some cases, also constitute an offence under the CDSA).

Duration

This exemption expires on the earliest of the following three dates:

- the date of revocation;
- the date on which this exemption is replaced by another exemption; or
- August 4, 2021.

You should be aware that there has been limited research into the safety of psilocybin for medical use. Because psilocybin is not an approved therapeutic substance, the availability of scientific evidence demonstrating the safety and efficacy of psilocybin is limited.

All of the potential health risks associated with psilocybin may not yet have been identified. It is therefore recommended that you continue to assess whether the potential benefits associated with the use of psilocybin continue to outweigh the risks.

This exemption is granted on the understanding that you and your supporting practitioner assume the risks associated with the use of psilocybin. In granting you this exemption, Health Canada does not guarantee that the use of psilocybin will not have some adverse effect on your health.

Health Canada has not approved psilocybin as a drug under the Food and Drugs Act and the Food and Drug Regulations. Health Canada has not approved the main active ingredient of psilocybin, as a drug under the *Food and Drugs Act* and the *Food and Drug Regulations*. There are no products containing psilocybin approved as therapeutic drugs in Canada.

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