Herbert, Catherine (HC/SC)

From: Doorn, Shannon (HC/SC)
Sent: 2020-11-03 1:55 PM
To: Barber, Kim (HC/SC)
Cc: EXEMPTION (HC/SC)
Subject: FYI: Call Summary HPFB Psilocybin

Hi Kim,

Below is a quick summary of the call with HPFB yesterday regarding psilocybin health professionals.

Thanks,
Shannon

On Monday, November 2, 2020, representatives from CSD had a call with HPFB (Patrick Stewart and Carole Legare) regarding the 18 requests with CSD from health professionals to consume psilocybin mushrooms for training purposes. The meeting opened with an overview of the applications, including details as to why these are not considered medical or scientific exemption requests. Given that the health professionals feel they need the experiential component of consuming psilocybin in order to better treat their patients with psilocybin-assisted psychotherapy, this is considered the complementary piece to the patient-specific psilocybin exemptions that have been issued.

The experts that have been consulted in the review of these applications have strongly indicated that personal experience with psilocybin is required in order to safely guide patients through treatment sessions. HPFB indicated that at a high level, this sounds acceptable, however, there are general concerns around the fact that there isn't a lot of evidence to support therapeutic uses of psilocybin. Ideally, a blinded clinical study with appropriate controls and research ethics board oversight would be done to develop the evidence. It was stated that there are ways that a CT could be designed in order to investigate the outcomes of this training model. OCT offered to provide guidance to TheraPsil regarding the CT process, should this be of interest to TheraPsil in the future.

Wang, Shan (HC/SC)

From: Spadaccini, Cesare (HC/SC)
Sent: 2020-08-19 3:40 PM
To: Wang, Shan (HC/SC)
Cc: Huard, Michelle (HC/SC)
Subject: FW: Call Summary OCT Meeting on psilocybin

Categories: Psilocybin

FYI - please note for health practitioner's exemption

Ces

-----Original Message-----
From: Kozlowski, Mark (HC/SC) <mark.kozlowski@canada.ca>
Sent: 2020-08-19 3:36 PM
To: Loo, Paul (HC/SC) <paul.loo@canada.ca>; Spadaccini, Cesare (HC/SC) <cesare.spadaccini@canada.ca>; Lee Choon, Jenny (HC/SC) <jenny.leechoon@canada.ca>
Cc: Huard, Michelle (HC/SC) <michelle.huard@canada.ca>; Kim, Claire (HC/SC) <claire.kim@canada.ca>; Abraszko, Julia (HC/SC) <julia.abraszko@canada.ca>
Subject: FYI: Call Summary OCT Meeting on psilocybin

On Tuesday, August 18, 2020, CSD had a call with representatives from the Office of Clinical Trials (OCT) regarding clinical studies by TheraPsil involving psilocybin.

The following input was requested from OCT:
1) Can TheraPsil practitioners participate in a study if they are also the sponsor?
2) Have previous requests been received from practitioners looking to participate in studies themselves?
3) Is there any new guidance or advice OCT can provide?

OCT expressed that there are major concerns with sponsors participating in studies, particularly due to conflict of interest. In addition, academic clinical trials are required to have physicians as investigators. Physicians cannot treat themselves unless for a minor condition or emergency, and cannot self-prescribe controlled drugs. Physicians cannot be impaired by drugs while responsible for patient care and treatment.

There have been no cases where an applicant has requested a study for educational purposes. There is one specific instance where a psychiatrist used a study drug in the context of a trial because he required it for medical reasons. OCT indicated that while possible to request a trial in healthy volunteers, this not common and typically used to establish dosing. Since there are already a number of studies globally on psilocybin dosing, this request is not feasible.

Ethically, investigators can’t switch between observing and participating unless they suffer from the condition being treated. Due to potential bias in favour of treatment, practitioners may downplay discomfort or under report adverse events.

If a non-participating physician were willing to conduct the study this would not be feasible due to the risk of exposing patients to the drug. Since dosing information is already known, the study is not considered necessary.

Professionally, practitioners would need to refrain from treating patients until there is no more drug in their system. Along with ethical concerns and no clear benefit, the risks don’t justify exposure.

OCT would prefer to see studies with GMP manufactured psilocybin as opposed to mushrooms.

A clinical trial is not possible for the situation TheraPsil is requesting.

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