Psygen

Office of Legislative and Regulatory Affairs
Controlled Substances Directorate
Health Canada

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Dear Sir or Madam,

Health Canada announced a proposed intent to revise the Special Access Program (the "**SAP**") on December 12, 2020. The proposal includes a suggestion to amend Part C of the *Food and Drug Regulations* (the "**FDR**"), reversing a 2013 amendment to Part C of the FDR that excluded restricted drugs (i.e. controlled substances scheduled to Part J of the FDR) from the SAP. Restricted drugs include LSD, MDMA, DMT, psilocybin and other controlled substances. The proposed amendment to Part C of the FDR would allow healthcare practitioners ("**HCPs**") to apply for access to restricted drugs on behalf of their patients for serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable.

Health Canada's proposal is to amend Part C of the FDR to allow access to restricted drugs through the SAP, and specifically to repeal subsections C.08.010(3) and C.08.011.1(2), which each read as follows: "*The Minister must not issue a letter of authorization for a new drug that is or that contains a restricted drug as defined in section J.01.001*". This expanded SAP will allow practitioners, on behalf of patients with a serious or life-threatening condition, to request access to restricted drugs through the SAP.

Psygen Industries Ltd. ("**Psygen**") would like to acknowledge our support for Health Canada's progressive proposal. However, we believe that expansion of the SAP to include restricted drugs should be treated as an important and interim first step toward a safe, regulated and equitable access system for psychedelic drugs, and not as a definitive solution to providing access to restricted drugs or as an interim stopgap while drug products are commercialized through the *Food and Drugs Act*. Such a system would provide access to psychedelics either directly to patients or to HCPs for use in support of psychotherapy or for other therapeutic purposes. The proposed amendment to Part C of the FDR is an improvement to the scope of the SAP, and while positive, does not fully address the broader need for federal regulations that provide nationwide access to restricted drugs from a regulated source for any therapeutic purpose as endorsed by a physician or other appropriate HCP in a medical document.

We also propose that the SAP be administered with respect to restricted drugs in such a way that HCPs are able to use psychedelic drugs intended for use in psychedelics-assisted psychotherapy for their own experiential education. Patient wellbeing is strongly served by allowing HCPs to freely discuss their own psychedelic experiences with a patient, particularly a patient having no firsthand experience with psychedelics.

Through the SAP and any subsequent regulatory framework, we believe that a significant amount of epidemiological and other safety data will be acquired related to psychedelics that already have established safety profiles – at least including LSD, MDMA, DMT and psilocybin. We hope that this data may facilitate a progression of policy on sale of some psychedelics into a wellness market, perhaps at sub-threshold doses (also called "microdoses") and potentially including a supervised and controlled setting at a retreat or similar context.

It is Psygen's hope that through amendments to part C of the FDR broadening the SAP to include restricted drugs, patients and HCPs will be able to access synthetic LSD, MDMA, DMT, psilocybin or other psychedelics that are manufactured in compliance with good manufacturing practices ("**GMP**"), dried fruiting bodies of mushrooms or dried plants cultivated in accordance with standards similar to good production practices ("**GPP**") defined in the *Cannabis Regulations*, or other classes of dried or extracted products manufactured in accordance with standards similar to GPP. We feel that patients and HCPs should be free to choose between natural and synthetic products, depending on the preference of the patient and the advice of the HCP.

Where there is substantial safety data available, such as with LSD, MDMA, DMT and psilocybin, we propose that reasonable dosages and protocols recommended by experienced HCPs for mental health conditions such as end-of-life distress, post-traumatic stress disorder, treatment resistant depression, and other appropriate conditions be considered for access through the SAP. We believe that for any such restricted drug, supply of drug substance to a pharmacist for compounding will provide a safe and cost-effective means for patients to access psychedelic therapies, and that it would be a failure of the SAP to only allow access to formulated drug products that are currently in clinical trials or approved in other jurisdictions. To this end, we propose that any licensed dealer able to manufacture a restricted drug in accordance with GMP standards be considered an acceptable source of drug substance for the SAP, including where compounding by a pharmacist or another licensed dealer is necessary prior to use of the restricted drug by a patient.

Psygen's subsidiary, Psygen Labs Inc., is an applicant to hold a dealer's licence under Part J of the FDR to manufacture and otherwise deal with LSD, MDMA, DMT and psilocybin (among other substances). Our team has significant experience working with a licensed dealer that is authorized to work with each of these substances. Psygen has a willingness and competency to provide any of these substances manufactured in accordance with GMP standards for use by exemption holders or through an expanded SAP.

We believe that amendment of part C of the FDR broadening the SAP to include restricted drugs is a crucial first step in helping patients to obtain a legal and safe supply of their medicine from a licensed dealer where other restricted drugs could be beneficial. As above, we feel that given the strong evidence-based safety profile of at least LSD, MDMA, DMT and psilocybin, access to these substances at well-defined dosage levels can be carried out safely, efficaciously and cost-effectively. We also suggest that approval of psychedelic-assisted psychotherapy through subsection 56(1) exemptions and hopefully through the SAP, demonstrates that there is a context in which the benefits of responsible use of some restricted drugs outweigh the harms. As a result, if an expanded SAP, a medical access system specific to psychedelics or ongoing clinical trials confirm the safety and efficacy of psychedelic-assisted psychotherapy, it also may serve the interests of Canadians to consider whether some of these substances should be broadly accessible and available for wellness and absent any specific pathology or diagnosis.

Sincerely,

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