MAPS CANADA

DECEMBER 2023

Special Access Program

Tip Sheet for providers, suppliers, and patients.

DEVELOPED BY

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DESIGNED BY

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The content in this document provides general educational information about regulatory pathways and does not advertise, promote, or recommend any drug, therapy, or medical intervention. It should not be used to diagnose, treat, or guide individual patient care. All decisions regarding treatment or access pathways must be made by licensed prescribers in the context of a patient care relationship. This document mentions health products the safety and effectiveness of which are still under investigation and that Health Canada has not yet granted market authorization in respect of. This document is an independent initiative of MAPS Canada and should not be interpreted as approved, reviewed by or endorsed by Health Canada.

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EMPOWER

ABOUT MAPS CANADA

Founded in 2011, MAPS Canada is a registered Canadian charitable organization.With hundreds of volunteers from across Canada, MAPS Canada is moving forward to become the leading Canadian source of information, resources and advocacy regarding psychedelic medicine and related multidisciplinary research, education, and public policy.

ABOUT THE SAP TIP SHEET

Welcome to the first edition of the MAPS Canada SAP Tip Sheet! This is a helpful and timely resource for patients, healthcare providers and suppliers (SAP stakeholders) looking to access Psychedelic-Assisted Therapy (PAT) through Health Canada's Special Access Program. Included is a detailed overview of the application process, common responses from Health Canada, relevant questions and answers, in addition to SAP templates and other helpful resources. At present, the focus is centred around Psilocybin and MDMA, as these are the two psychedelic compounds Health Canada has approved applications for thus far. All of the information provided in this document has been taken from the Health Canada website or expertise shared by stakeholders from our SAP Community of Practice. MAPS Canada have compiled these resources to simplify and expedite the SAP application process for you. We understand that you are busy, and it is our intention that the SAP Tip Sheet can play a role in making legal PAT more accessible.

We will be updating this document as policies and practices evolve. Please join SAP Community of Practice if you would like to inform updates to the SAP Tip Sheet and engage in rich discourse.

Please refer to the table of contents and clickable links throughout the document for navigation to different sections and access to further resources.

BECOME A MEMBER OF OUR COMMUNITY OF PRACTICE TODAY!

MAPS CANADA

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TERMINOLOGY

DEFINITIONS

Healthcare Practitioner (Prescriber): For the purpose of Health Canada, Healthcare Practitioner refers to professionals who can prescribe drugs in their relevant province or territory. They can be medical doctors or nurse practitioners. They are the primary applicants for SAP and are liable for their patients' treatment.

Allied Healthcare Provider: Non-prescribing healthcare workers including nurses and therapists. They are primarily involved in providing service during the preparation, administration, and/or integration stages of therapy. They may assist a prescriber in preparing the SAP application, but will not be listed on the application.

Patient: Receiver of therapy approved by SAP. Typically conventional treatments have been tried, failed, or are unsuitable/unavailable for patients with serious or life-threatening conditions.

Supplier: Drug manufacturer with Good Manufacturing Practice status who supplies the medicine to prescribers with Letter of Authorization from Health Canada.

ACRONYMS

GMP: Good Manufacturing Practice
HC: Health Canada
LoA: Letter of Authorization
PAT: Psychedelic-Assisted Therapy
SAP: Special Access Program
SAP CoP: Special Access Program Community of Practice

MAPS CANADA

TABLE OF CONTENTS

This document mentions health products the safety and effectiveness of which are still under investigation and that Health Canada has not yet granted market authorization in respect of.

The SAP Application Process

A step-by-step overview of the SAP application process, ensuring compliance with requirements based on Health Canada guidelines.

1. BEFORE MAKING THE REQUEST:

Healthcare Prescriber (HCP), Allied Healthcare Provider(s) and Patient confirm the availability of sufficient evidence supporting the use, safety, and efficacy of the drug for the specific patient's condition.

2. COMPLETING THE SAP REQUEST FORM (FORM A):

- [ ] **Provide the name of the drug being requested.**
- [ ] **Specify the quantity of the drug required.**
- [ ] **Identify the drug manufacturer's name. See the list of SAP suppliers**
- [ ] **Describe previously attempted or considered treatments and their outcomes.**
- [ ] **Provide information regarding the use, safety, and efficacy of the drug for the patient's condition. See the list of academic evidence.**
- [ ] **Include the name and civic address of the practitioner to whom the drug will be shipped.**
- [ ] **Include any additional information requested by Health Canada to aid the authorization decision.**
- [ ] **Ensure compliance with all provincial/territorial regulatory body requirements.**

Health Canada / Santé Canada

Protected B when completed

Special Access Program
Form A - Patient specific request - C08.010(1)

Section A: Practitioner information

Practitioner's name: (First Last)

Hospital or clinic name:

Practitioner's address:

City: Province: Postal Code:

Telephone #: Fax #:

Email:

If alternate contact is available complete section below

Alternate contact name: (First Last)

Telephone #: Fax #:

Email:

Shipping information

Send drug c/o:
☐ In-patient hospital pharmacy ☐ Practitioner's office ☐ Nuclear medicine
☐ Blood bank ☐ Government agency depot ☐ Community Pharmacy

Shipping address:

City: Province: Postal Code:

Telephone #: Fax #:

Section B: Drug and manufacturer information

Manufacturer: (name and location)

Trade name:

Other name(s):

PDI#:

Route of administration: ☐ Oral ☐ I.V. ☐ I.M. ☐ Topical ☐ S.C. ☐ Other:

Dosage form: ☐ Tab ☐ Cap ☐ Liquid ☐ Powder ☐ Cream ☐ Oint. ☐ Patch ☐ Other:

Canada

Community of Practice Suggestions

The following should be considered in the application:

- Psychiatric History:
  - Longstanding medical condition (e.g., Treatment Resistant Depression, Major Depressive Disorder, Post Traumatic Stress Disorder, End of Life Distress).
  - Suicidal ideation may be approved. Family history of bipolar disorder or schizophrenia may not be approved.
  - Currently experiencing low mood, fatigue, insomnia, feelings of anxiety, feeling overwhelmed, and so forth not due to work, home, or typical life stressors.
  - Note: Health Canada has approved complex patients.
- Patient should be compliant with current psychotropic medication.
- A comprehensive list of treatments tried and NOT tried for medical condition.
  - Must have tried psychotherapy (e.g., Cognitive Behavioural Therapy).
  - It is not a requirement that the patient has tried ketamine or neurostimulation treatments (e.g., Electroconvulsive Therapy, Repetitive Transcranial Magnetic Stimulation), however, justification may be requested.
- Relevant Scores (can be helpful to include at least one):
  - QIDS-SR
  - GAD-7
  - PHQ-7
  - QBQ-R
  - Sheehan Disability Scale
- Can be helpful to attach full the text of research studies in the application document, particularly when there is push back from Health Canada.
- Refer to Psychedelic-Assisted Therapy (PAT) guidelines
  - Professional Practice Guidelines for Psychedelic-Assisted Therapy

3. AUTHORIZATION DECISION PROCESS:

Health Canada:

- Evaluates if conventional treatments have been tried, failed, or deemed unsuitable/appropriate for the patient.
- Should not question the practitioner's diagnosis or recommended treatment option.
- May request additional information.

4. MANUFACTURER CONFIRMATION & LICENSING:

Health Canada:

- Requests confirmation from the manufacturer regarding their willingness and ability to sell the drug for the indicated use.
- Psychedelic drugs should be available in a **dosage form** and, except for rare circumstances, should meet **Good Manufacturing Practices (GMP)**.

If the manufacturer is in Canada:

- Confirm they are a licensed dealer under the Controlled Drugs and Substances Act.
- Verify that the restricted drug is listed on their license.

If the manufacturer is outside Canada:

- Confirm that the importing dealer is licensed.
- Verify that the restricted drug is listed on their license.
- Ensure the importing dealer has obtained an import permit from Health Canada.

This document mentions health products the safety and effectiveness of which are still under investigation and that Health Canada has not yet granted market authorization in respect of.

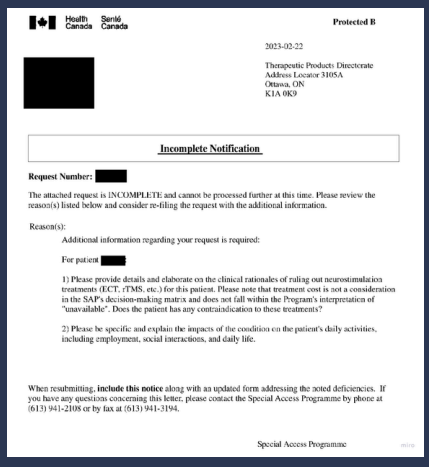
5. AUTHORIZATION ISSUANCE:

Health Canada (HC) can issue…

Incomplete Notification
HC is requesting additional information (e.g., patient medication history). NOT a Letter of Denial.

Letter of Authorization
Manufacturer can legally sell the specified quantity of the drug to the requesting HCP for their patient.

Letter of Denial
Note: You may bring the application for judicial review in the Federal Court to overturn the denial. HC denies based on their internal policies. The Charter supersedes all policies.



Health Canada / Santé Canada — Protected B

2023-02-22

[redacted]

Therapeutic Products Directorate
Address Locator 3105A
Ottawa, ON
K1A 0K9

Incomplete Notification

Request Number: [redacted]

The attached request is INCOMPLETE and cannot be processed further at this time. Please review the reason(s) listed below and consider re-filing the request with the additional information.

Reason(s):

Additional information regarding your request is required:

For patient [redacted]

1) Please provide details and elaborate on the clinical rationales of ruling out neurostimulation treatments (ECT, rTMS, etc.) for this patient. Please note that treatment cost is not a consideration in the SAP's decision-making matrix and does not fall within the Program's interpretation of "unavailable". Does the patient has any contraindication to these treatments?

2) Please be specific and explain the impacts of the condition on the patient's daily activities, including employment, social interactions, and daily life.

When resubmitting, **include this notice** along with an updated form addressing the noted deficiencies. If you have any questions concerning this letter, please contact the Special Access Programme by phone at (613) 941-2108 or by fax at (613) 941-3194.

Special Access Programme

[redacted]

2023-02-09

Therapeutic Products Directorate
Address Locator 3105A
Ottawa, ON
K1A 0K9

Letter of Authorization

Request Number: 166631
Notwithstanding Section C.08.002 of the *Food and Drug Regulations*, you are authorized to sell to:

[redacted]

Ship to: Practitioner's Office

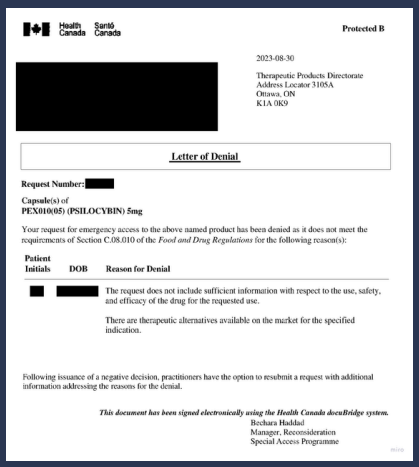
3 X Capsule(s) (**0** on hand, **3** to be shipped) of
PEX010(25) (PSILOCYBIN) 25mg
for the emergency treatment of:

Patient Initials	DOB	Sex	Quantity	Drug Form	Indication
[redacted]			3	Capsule(s)	Major depressive disorder NOS

The above named practitioner has complied with the requirements listed in Section C.08.010 of the *Food and Drug Regulations* to obtain the above mentioned drug for use as indicated under his/her professional responsibility. In doing so, the practitioner has agreed to report to you and to Health Canada, the results of this emergency use. Practitioners must also, upon request, account for all quantities received. The sale is hereby exempt from all other provisions of the *Food and Drugs Act* and the *Food and Drug Regulations*.

To facilitate importation/shipment, please label package as follows: 'URGENT-EMERGENCY DRUG' and ensure that a copy of this letter accompanies the package. If you have any questions concerning this letter, please contact the Special Access Programme by phone at (613) 941-2108 or by fax at (613) 941-3194.

This document has been signed electronically using the Health Canada docuBridge system.
Ian MacKay
Manager
Special Access Programme



Health Canada / Santé Canada — Protected B

[redacted]

2023-08-30

Therapeutic Products Directorate
Address Locator 3105A
Ottawa, ON
K1A 0K9

Letter of Denial

Request Number: [redacted]

Capsule(s) of
PEX010(05) (PSILOCYBIN) 5mg

Your request for emergency access to the above named product has been denied as it does not meet the requirements of Section C.08.010 of the *Food and Drug Regulations* for the following reason(s):

Patient Initials	DOB	Reason for Denial
[redacted]	[redacted]	The request does not include sufficient information with respect to the use, safety, and efficacy of the drug for the requested use. There are therapeutic alternatives available on the market for the specified indication.

Following issuance of a negative decision, practitioners have the option to resubmit a request with additional information addressing the reasons for the denial.

This document has been signed electronically using the Health Canada docuBridge system.
Bechara Haddad
Manager, Reconsideration
Special Access Programme

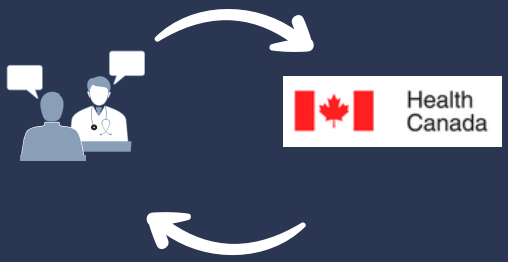
6. ONGOING TREATMENT & REPORTING:

HCP and Patients:

- If using the drug for continued treatment, must complete section E2 of Form A.
  - Describe the patient's response to the drug relative to initial treatment goals.
- Use the SAP follow-up form (Form C) for reporting when the drug is requested only once and won't be requested again.

7. ACCOUNTING & COMPLIANCE:

HCP, the prescriber, must be prepared to account for all received drug quantities upon request by **Health Canada**. They are accountable for patient outcomes in perpetuity.



For more information on the process for submitting a request to the SAP and the practitioner's reporting requirements, please consult the guidance document or contact Health Canada:

Special Access Program for drugs: Guidance document for industry and practitioners.

Special Access Program
Health Canada, Tunney's Pasture
Address Locator 3105A
K1A 0K9

Telephone: 613-941-2108
Fax: 613-941-3194
E-mail: sapd-pasm@hc-sc.gc.ca

GMP Suppliers for SAP

Health Canada requires manufacturers to be **Good Manufacturing Practices (GMP)** certified. **The following manufacturers are eligible, have previously supplied SAP and have stock available as of December 2023**. The information below is sufficient for a clinician to complete the SAP application. After receiving the **Letter of Authorization (LoA)** from Health Canada, the manufacturer and prescriber can arrange for delivery. Note: Pricing may be subject to change.

Filament Health

Product: PEX010 25 mg Psilocybin (Natural extract of Psilocybe cubensis)

Contact: sap@filament.health

Additional Information:

- One capsule of PEX010 25 mg psilocybin per treatment session. Practitioners usually request up to 3 capsules for 3 sessions via SAP.
- Filament provides the drug at no cost.

PharmAla

Product: LaNeo MDMA 40mg Capsule (Synthetic)

Contact: sap@pharmala.ca

Additional Information:

- Four capsules of LaNeo MDMA per treatment - 120mg to start, and a subsequent 40mg at the discretion of the therapist.
- $500 per treatment; $1500 per 3-month course of treatment.

Psygen

Product: Psygen's Psilocybin 25 mg (Synthetic powder in vial)

Contact: sales@psygen.ca

Additional Information:

- All Psygen's Psilocybin accessed through MAPS Canada will be free of charge to the patient.

Common Health Canada Responses

Some Health Canada reviewers may ask for more information than others. These are common responses collected from providers' experiences. Responses are suggestions informed by Community of Practice meetings.

HEALTH CANADA: We recommend that this patient applies to be a part of a ***clinical trial*** to treat their medical condition.

PRESCRIBER: Clinical trial is not ideal for this patient.

- The majority of psychedelic clinical trials have strict and rigid inclusion/exclusion criteria. For example, this patient has a history of **[head injury, substance abuse, anxiety, etc.]** which would make them ineligible for most trials.
- Enrolling in clinical trial does not guarantee treatment, as participants are randomized into treatment or placebo group.
- There are currently no clinical trials enrolling in the patient's area.
- The patient cannot wait longer to treat their critical and terminal medical condition

HEALTH CANADA: We recommend that you (prescriber) conduct an ***Open Label Individual Patient (OLIP) study*** for the patient.

PRESCRIBER: I do not have the time and resources to conduct an OLIP study for the patient. To conduct one, I would need to take time off my regular practice to do the paperwork, gain approvals, conduct the trial, and analyse the results. This would harm other patients' health by reducing the time I have to care for them. This would violate my medical ethical responsibilities. **[If applicable:]** This patient is not eligible for an OLIP study because their condition is serious but not life-threatening.

Common Health Canada Responses

HEALTH CANADA: ***Ketamine*** is a viable psychedelic treatment available by prescription.

PROVIDER: This is not necessarily appropriate for the conditions being applied for. The research does not indicate efficacy of ketamine for **[condition].** Regarding the anti-depressant effects of ketamine, much of the research indicates the effect is a rapid-onset effect, whereas research on psilocybin-assisted psychotherapy indicates a potential long term antidepressant effect. Further, ketamine clinics vary in cost and treatment program, which may not be suitable for this particular individual.

HEALTH CANADA: Please confirm that the product will be received by a practitioner or pharmacist. Please specify how the product will be stored.

PROVIDER: The practitioner will be present to received the product. It will be stored in a locked safe, which only I am able to access.

HEALTH CANADA: Please be specific and explain the impacts of the condition on the patient's daily activities including employment, social interactions, and daily life.

PROVIDER: [Obtain this information from the patient, and include at least 1 short paragraph on each of employment, social interactions, and daily life]

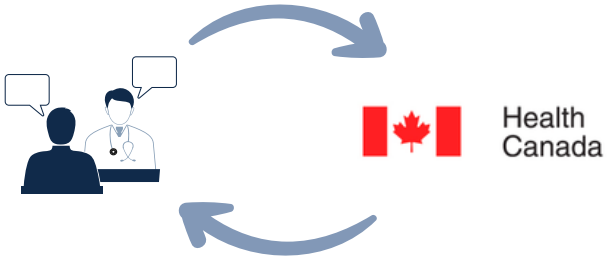
Common Health Canada Responses

HEALTH CANADA: We recommend that this patient applies to undergo **[ECT, SSRIs]** to treat their **[condition]**.

PROVIDER: The aforementioned recommendation is not suitable for this patient.

Example #1: Some potential risks of ECT include short-term memory loss, confusion, cognitive impairments, and in some cases, physical complications like headaches, nausea, and muscle pain. Additionally, there is a concern about the anxiety and reluctance in this individual considering the treatment.

Example #2: Some potential risks of SSRIs include nausea, diarrhea, headaches, insomnia, drowsiness, and sexual dysfunction. In some cases, especially during the early stages of treatment which is arguably the most vital, SSRIs can lead to an increase in suicidal thoughts, particularly in young adults. Additionally, long-term use of SSRIs has been associated with concerns about potential effects on bone health, as well as the possibility of developing tolerance over time. Discontinuation of SSRIs can be challenging due to withdrawal symptoms.



The SAP Application

Questions from SAP stakeholders.

To view the answers, scroll down or click the question link below.

1. Can a non-prescribing Allied Health Care Provider submit a SAP application?

A therapist, counsellor, social worker, medical office assistant, nurse, pharmacist, or any other non-prescribing Health Care Professional may assist with the completion of an official SAP application, however, officially a healthcare practitioner (see definition below) must review and sign the document. This individual would then ultimately be legally and professionally responsible for submitting the SAP application as per Health Canada guidance.

Note: "a practitioner is a person who (a) is entitled under the laws of a province to treat patients with a prescription drug, and (b) is practicing their profession in that province. Source: Health Canada Special Access Program for Drugs: Guidance Document for Industry and Practitioners

2. How long does the approval process typically take from start to finish?

Based on providers' experiences, the application can take 2-10 hours to write from scratch, or 10-30 minutes with templates. See available templates on Page 26.

Approval from Health Canada can take anywhere between 2-6 weeks depending on:

- Urgency – if patient is critically or terminally ill. This must be communicated to Health Canada directly at the top of your application or via call.
- Additional information request(s) from Health Canada to the prescriber. See Common Health Canada Responses on Page 8.
- Backlog of pending SAP requests.
- Indication being applied for (new versus already approved). Previous indications that have been approved for SAP include Psilocybin for Major Depressive Disorder/Treatment Resistant Depression/End of Life Distress, and MDMA for Post-Traumatic Stress Disorder (PTSD).

3. How do I choose the right supplier when completing an application? What is the best way to contact a supplier before completing an application?

It is important to choose a supplier that actually has product available and in stock prior to submitting an application. There have been situations in the past where an application is approved by Health Canada but treatment was delayed due to the chosen manufacturer not having a supply of stock readily available. MAPS Canada is pleased to maintain an updated list of SAP supply companies and can assist with connecting any patient or provider with an appropriate SAP product manufacturer. See current *GMP suppliers for SAP* list on Page 10.

We encourage you to connect with the manufacturer prior to submitting a SAP application to confirm if inventory is available, request product information and build a relationship with the supplier.

4. Is there a cost associated with the application process?

There is no fee for applying to the SAP in Canada; however, potential costs could arise at any point where professional services are involved.

Some examples of where cost may arise:

- Prescriber/provider may choose to charge a fee for the time required to screen patient and complete the SAP application.
- Purchasing medication from the supplier.
- Compensating provider's time for counselling and therapy sessions (e.g., preparation, administration, and integration).
    - Note: Prescribers should not be doing PAT alone. Collaboration with therapist and interdisciplinary healthcare team is recommended.

5. What is the cost of ordering psilocybin or MDMA from a supplier?

Per Health Canada guidance, the decision to charge for a requested drug authorized by the SAP rests with the manufacturer. Manufacturers are responsible for determining prices and they should be contacted directly to request this information.

Pricing for psychotherapy will vary between practitioners/clinics and the required length of time for therapy may vary based on each patient's individual needs. PAT requires professional oversight during the treatment as well. So, there may be a cost for therapy before, during, and after a session with medicine. Therapists have varying service rates, thus MAPS Canada cannot provide a specific overall cost estimate. Therapists often have sliding scale payment options for those who may be able to afford more or less.

Additionally, overall financial constraints may be reduced for clients who are able to utilize extended health coverage and/or benefit plans to offset the costs of associated therapy.

6. What are the most common mental health conditions that Health Canada approves for treatment with psilocybin or MDMA through the SAP?

Currently, the indications that have been authorized by Health Canada include:

- Psilocybin for Major Depressive Disorder, Persistent Depressive Disorder, Treatment Resistant Depression, and End of Life Distress.
- MDMA for PTSD.

Please see *SAP Templates* based on authorized indications on Page 26.

MAPS Canada hopes to see more approved indications in the future and is taking steps to expand this list for the benefit of all Canadian patients now and in the future.

7. Which conventional mental-health treatments should be exhausted before completing a SAP application?

It is best practice to provide a detailed patient history on the application including strong justification for what treatments have and have not been tried. In order to be approved for the SAP it is important to demonstrate that conventional treatments have been tried, failed, or are unsuitable/unavailable for patients with serious or life-threatening conditions.

Depression Treatment Guidelines

PTSD Treatment Guidelines

8. How many references should be included in a SAP application? Which studies are best referenced to support an application for psilocybin or MDMA-assisted therapy?

There is a significant pool of scientific evidence to draw upon for properly supporting an application and the quantity and quality of research continues to improve over time. The research community at MAPS Canada continues to explore the many benefits of psychedelic therapy and maintains an up-to-date list of relevant scientific literature that may be used to further support an application for PAT.

As suggested by members in our community of practice, it can be helpful to attach the *full text* of research studies in the application document, particularly when there is push back from Health Canada.

A list of over 100 medical literature summaries providing research evidence is available, categorized by treatment and condition.

Psychedelic-Assisted Therapy

Questions from SAP stakeholders.

To view the answers, scroll down or click the question link below.

7. How long does it take for the effects of psilocybin and MDMA to begin? How long do sessions typically last?

8. Are there any recommended safety protocols for clients after the psychedelic experience?

9. What permissions are needed from a therapist's regulating body and insurance provider to perform psilocybin or MDMA-assisted therapy?

1. How can I best support clients in accessing psilocybin or MDMA assisted treatment?

Clinical trials are the most encouraged route from Health Canada's perspective. However, Health Canada's SAP is the best route if patient cannot access or is ineligible for clinical trials.

2. What are the recommended doses of psilocybin and MDMA for therapy? Are clients titrated up or down over sessions depending on the initial outcome?

Psilocybin: A 25 mg dose is the maximum dose approved by Health Canada to date. Lesser doses are available, but have NOT been approved yet.

MDMA: The recommended dose is 120 mg with a possible top-up at the 60-90 minute mark, if deemed necessary. 160 mg is the maximum allowable dose. Lower doses can be used.

3. How much psilocybin or MDMA should therapists request for each client if there is a plan to administer treatment over multiple sessions?

Psilocybin: 2 or 3 doses of 25 mg psilocybin.

MDMA: Up to 3 doses of 160 mg MDMA.

Note: Multiple sessions does NOT mean on the same day.

4. What is the appropriate setting and approach for PAT?

Setting

In general, Health Canada released guidelines on the expectations regarding therapists and settings for clinical trials: *A psychologically safe environment is essential for the duration of the acute drug effects. The setting under which the drug is administered can play an important role in the reduction of the psychological risk associated with the administration of the drug. Consequently, the sponsor may wish to consider selecting a room where the drug is administered that is furnished and decorated in a way that is comfortable and calming for participants. Contingency plans should be established for potential serious adverse events.*

As SAP is not as closely monitored as clinical trials, some flexibility in the facility is allowed. Provider should discuss what the most appropriate setting is with their client.

Therapeutic Approaches

It is up to the provider and client to determine the most appropriate frameworks and modalities for facilitating PAT. There is no one-size-fits-all approach to therapy.

In general, PAT typically consists of three phases:

1. *Preparation:* offering information, establishing safety and agreements, setting intentions, developing client-therapist rapport, client risk assessments, number of sessions depend on complexity of client's condition.
2. *Administration (Psychedelic Experience)*: two therapists or guides in the room (medical professional must be reachable), generally non-directive (client goes "inwards") but can also be psycholytic (engaging with therapist), all day sessions.
3. *Integration:* post-experience meaning-making, continue to target intentions with therapists or on client's own terms.

5. Which health professionals should be involved and at what stage of PAT?

A PAT therapist should be involved at all three stages – preparation, administration, and integration. Health Canada guidelines state that during the administration phase, there should be a minimum of two therapists or guides present. As well, the therapists should remain the same throughout multiple therapeutic sessions to maintain rapport and trust.

A medical professional (e.g., physician, nurse, nurse practitioner) should be involved in the preparation stage, where they help screen client's appropriateness for PAT. They also administer the psychedelic medicine and must be reachable to provide medical oversight, intervening at any point. This person assumes responsibility for all medical acts, and must follow up with client after treatment and report back to Health Canada.

6. What type of safety equipment is required on-site when performing PAT?

For safety, an accredited therapist or guide must be onsite for typically four to six hours, however, this may be up to eight hours or more depending on the clients. It is also recommended to have a comprehensive first aid kit available, as well as emergency abortive medications or support medications if needed. Please refer to your provincial guidelines for PAT. For example, Alberta recommends the following items for a PAT first aid kit:

- Epinephrine IM - Anaphylaxis
- Diphenhydramine PO/IM/SC - allergy
- Dimenhydrinate PO/IM - nausea and vomiting
- Ondansetron PO/SL - nausea and vomiting*
- Lorazepam SL/IM/SC - severe anxiety or seizures
- Midazolam SC/IM/IN - seizures
- Olanzapine SL - "trip stopper"
- Naloxone IM/IN
- AED - cardiac arrest
- Glucometer + testing strips - hypoglycemia

*May be used but causes severe constipation so avoid in patients with abdominal metastatic disease

*Benztropine PO+IM (only if haloperidol/other typical antipsychotics will be administered)

Note: Contingency plans should be established for potential serious adverse events. There needs to be check-in visits in the days and weeks following administration of the drug due to a possible worsening of the participant's mental health following completion of PAT sessions.

7. How long does it take for the effects of psilocybin and MDMA to begin? How long do sessions typically last?

Psilocybin: Onset can take anywhere from 30 minutes to 3 hours.

MDMA: Onset can take anywhere from 30 to 45 minutes.

The duration of the experience will depend on several factors including dosage, the individual's metabolism and medication interactions. A full session of psilocybin or MDMA can last anywhere between **4 to 6 hours**. It is wise to plan for 4 to 6 hour sessions with buffer time to accommodate client's unique onset/offset time.

8. Are there any recommended safety protocols for clients after the psychedelic experience?

If treatment happens in the patient's own home, there is no concern for impaired driving and the patient can simply go to sleep. If treatment happens at the clinic, they must arrange for someone to pick them up. Any lodging, travel arrangements, and contingency plans should be worked out beforehand during the preparation stage.

9. What permissions are needed from a therapist's regulating body and insurance provider to perform PAT?

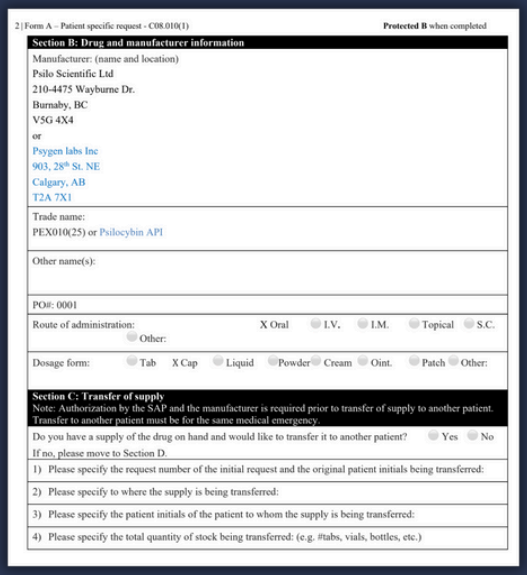
Every Health Care Professional is bound by the rules and guidelines of their own regulatory, licensing, and/or advocacy bodies. Additionally, each province or territory may have specific regulations surrounding the provision of PAT. For example, Alberta recently released their own Psychedelic Drug Treatment Services Standards, which were made pursuant to the Mental Health Services Protection Regulation under the Mental Health Services Protection Act. These standards, along with the Act and Regulation set the minimum requirements that a licensed psychedelic drug treatment service provider must comply with for the legal provision of psychedelic drug treatment services. Other provinces may develop similar legislation.

Please refer to your licensing bodies and insurance providers directly.

In addition, to prevent therapist regression, know yourself and the law. Iterative personal inquiry is always a good idea: Do you have proper PAT training? What is within your scope of work? Please refer to Ethical and legal issues in psychedelic harm reduction and integration therapy as a means to prompt personal inquiries.

SAP Templates

Shared by Community of Practice members.



2 | Form A – Patient specific request - C08.010(1) **Protected B** when completed

Section B: Drug and manufacturer information

Manufacturer: (name and location)
Psilo Scientific Ltd
210-4475 Wayburne Dr.
Burnaby, BC
V5G 4X4
or
Psygen labs Inc
903, 28th St. NE
Calgary, AB
T2A 7X1

Trade name:
PEX010(25) or Psilocybin API

Other name(s):

PO#: 0001

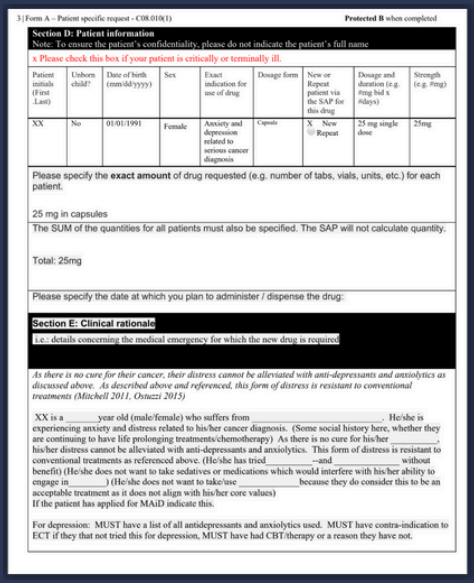
Route of administration: X Oral ○ I.V. ○ I.M. ○ Topical ○ S.C. ○ Other:

Dosage form: ○ Tab X Cap ○ Liquid ○ Powder ○ Cream ○ Oint. ○ Patch ○ Other:

Section C: Transfer of supply
Note: Authorization by the SAP and the manufacturer is required prior to transfer of supply to another patient. Transfer to another patient must be for the same medical emergency.

Do you have a supply of the drug on hand and would like to transfer it to another patient? ○ Yes ○ No
If no, please move to Section D.

1) Please specify the request number of the initial request and the original patient initials being transferred:
2) Please specify to where the supply is being transferred:
3) Please specify the patient initials of the patient to whom the supply is being transferred:
4) Please specify the total quantity of stock being transferred: (e.g. #tabs, vials, bottles, etc.)



3 | Form A – Patient specific request - C08.010(1) **Protected B** when completed

Section D: Patient information
Note: To ensure the patient's confidentiality, please do not indicate the patient's full name

x Please check this box if your patient is critically or terminally ill.

Patient initials (First ..Last)	Unborn child?	Date of birth (mm/dd/yyyy)	Sex	Exact indication for use of drug	Dosage form	New or Repeat patient via the SAP for this drug	Dosage and duration (e.g. #mg bid x #days)	Strength (e.g. #mg)
XX	No	01/01/1991	Female	Anxiety and depression related to serious cancer diagnosis	Capsule	X New ○ Repeat	25 mg single dose	25mg

Please specify the **exact amount** of drug requested (e.g. number of tabs, vials, units, etc.) for each patient.

25 mg in capsules

The SUM of the quantities for all patients must also be specified. The SAP will not calculate quantity.

Total: 25mg

Please specify the date at which you plan to administer / dispense the drug:

Section E: Clinical rationale
i.e.: details concerning the medical emergency for which the new drug is required

As there is no cure for their cancer, their distress cannot be alleviated with anti-depressants and anxiolytics as discussed above. As described above and referenced, this form of distress is resistant to conventional treatments (Mitchell 2011, Ostuzzi 2015)

XX is a _____year old (male/female) who suffers from _____. He/she is experiencing anxiety and distress related to his/her cancer diagnosis. (Some social history here, whether they are continuing to have life prolonging treatments/chemotherapy) As there is no cure for his/her _____, his/her distress cannot be alleviated with anti-depressants and anxiolytics. This form of distress is resistant to conventional treatments as referenced above. (He/she has tried _____--and _____ without benefit) (He/she does not want to take sedatives or medications which would interfere with his/her ability to engage in _____) (He/she does not want to take/use _____because they do consider this to be an acceptable treatment as it does not align with his/her core values)
If the patient has applied for MAiD indicate this.

For depression: MUST have a list of all antidepressants and anxiolytics used. MUST have contra-indication to ECT if they that not tried this for depression, MUST have had CBT/therapy or a reason they have not.

Psilocybin

- [Anxiety and Depression related to cancer diagnosis]
- [Depression (TRD/MDD) or End of Life Distress]

MDMA

- [MDMA for Post Traumatic Stress Disorder]

EMPOWER HEALTH
Transformative Healthcare Solutions

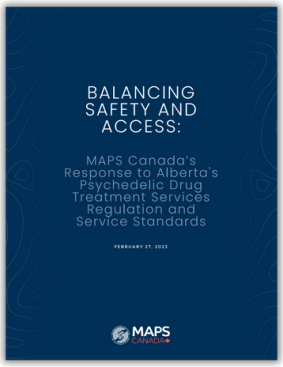
Thank you Dr. Joel Kailia MD, Madison Nobbs RN, and Dr. Valerie Kaye MD from Empower Health for sharing the MDMA SAP template! They are a community based integrated wellness centre providing transformative healthcare solutions and services such as medicine-assisted therapy including the use of ketamine and cannabis as well as MDMA and Psilocybin via the SAP.

Resources

Shared by members or created by MAPS Canada.

The SAP Community of Practice

Stay informed about the SAP and connect with fellow professionals! Sign up here.



Balancing Safety and Access

MAPS Canada's Response to Alberta's Psychedelic Drug Treatment Services Regulation and Service Standards.

Psychedelic-Assisted Psychotherapy Training

Current training opportunities available as of December 2023.

TheraPsil, a small non-profit training and advocacy organization who are establishing a trusted ecosystem for psychedelic medical professionals, offer extensive training and support for SAP Prescribers and healthcare professionals.

- Learn more about the Practical Implications for Psilocybin-Prescribers here
- Learn more about Fundamentals of Psilocybin-Assisted Psychotherapy Training here
- Learn more about MDMA-Assisted Psychotherapy Training here.

ATMA's Psychedelic-assisted Therapy Programs take you from training to practical application through our online and in-person learning environment. Students gain access to leading experts in the field through online courses, Live Q+A's and Self-Care program, which is their unique offering specifically created to support the mental well-being of practitioners. Graduates will receive continued support as a practitioner through in-person coaching, support services and network of clinics, as well as being listed on a global directory. ATMA is building and supporting the largest community of psychedelic practitioners and clinics in adopting psychedelic-assisted therapy. Their philosophy to begin with the healthcare provider, will lay a foundation for higher participation, increased accessibility, advanced clinical care, and safe effective delivery of psychedelic-assisted therapy.

- Introduction to Psychedelic-assisted Therapy (PaT) Course
- Advanced Psychedelic-Assisted Therapy (PaT) Certification Program

Get 10% Off ATMA PaT Training with Code: **MAPSCAN10**

Psychedelic-Assisted Psychotherapy Training

Current training opportunities available as of December 2023.

NUMINUS

Numinus has curated a robust certification pathway with busy learners in mind, to offer best-in-class training for providers looking to offer psychedelic services. They offer certification in ketamine, MDMA, and psilocybin which are taught by highly experienced industry leaders and they include valuable experiential learning opportunities. You can expect a clear path to practice with their training and the ability to offer safe and evidence-based care to clients in need.

- Fundamentals of Psychedelic-Assisted Therapy
- Molecular Foundations (3-Course Bundle)
- Psychedelic Harm Reduction and Integration: Introduction for Practitioners

Get 10% Off Numinus PaT Training with Code: **MAPSCAN10**

Thank You to Our Sponsor!

Empower Psychedelics is currently registered as a federal non-profit organization based in British Columbia, Canada.

Our mission is to expand access to psychedelics for medical professionals, establishing new use cases and settings for psychedelic-assisted therapies.

Empower Psychedelics
MAPS Canada Partnership